D.I. ____

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ETHYPHARM S.A. FRANCE, Plaintiff, v. ABBOTT LABORATORIES, Defendant.	C.A. No. 08-126 (SLR)

DECLARATION OF SEAN M. BRENNECKE, ESQ.

May 13, 2008

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ETHYPHARM S.A. FRANCE, Plaintiff, v. ABBOTT LABORATORIES, Defendant.	C.A. No. 08-126 (SLR)

DECLARATION OF SEAN M. BRENNECKE, ESQ.

SEAN M. BRENNECKE, ESQ., does hereby declare the following:

1. I am an associate in the firm of Bouchard Margules & Friedlander, P.A., counsel for defendant Abbott Laboratories ("Abbott") in this matter. I submit this Declaration in connection with Abbott's Opening Brief in Support of Its Motion to Dismiss.

2. Attached hereto as Exhibit "A" is a true and correct copy of the Complaint in Reliant Pharmaceuticals, Inc. v. Abbott Laboratories and Laboratories Fournier S.A. (D. Del. C.A. No. 04-350 (KAJ)).

3. Attached hereto as Exhibit "B" is a true and correct copy of the Development, License and Supply Agreement, dated as of May 7, 2001, among Ethypharm, S.A., Ethypharm Industries, S.A., and Reliant Pharmaceuticals, LLC, filed as Exhibit 10.29 to Form S-1/A with the U.S. Securities and Exchange Commission on August 5, 2005.

4. Attached hereto as Exhibit "C" is a true and correct copy of the First Amended Complaint in State of Florida et al. v. Abbott Laboratories et al. (D. Del. C.A. No. 08-155 (SLR)).

5. Attached hereto as Exhibit "D" is a true and correct copy of Direct Purchaser Class Plaintiffs' First Amended and Consolidated Class Action Complaint in In re TriCor Director Purchaser Litigation (D. Del. C.A. No. 05-340 (KAJ)).

6. Attached hereto as Exhibit "E" is a true and correct copy of End Payor Plaintiffs' Consolidated Class Action Complaint in In re TriCor Indirect Purchaser Antitrust Litigation (D. Del. C.A. No. 05-360 (KAJ)).

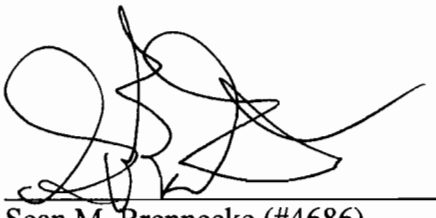
7. Attached hereto as Exhibit "F" is a true and correct copy of the Joint Answer and Counterclaims in Reliant Pharmaceuticals, Inc. v. Abbott Laboratories and Laboratories Fournier, S.A. (D. Del. C.A. No. 04-350 (KAJ)).

8. Attached hereto as Exhibit "G" is a true and correct copy of the Settlement Term Sheet, together with accompanying cover letter and related exhibits, in Reliant Pharmaceuticals, Inc. v. Abbott Laboratories, et al. (D. Del. C.A. No. 04-350 (KAJ)). Exhibit "G" is **HIGHLY CONFIDENTIAL – FILED UNDER SEAL PURSUANT TO COURT ORDER**.

9. Attached hereto as Exhibit "H" is a true and correct copy of News Release Issued by Oscient Pharmaceuticals Corporation on April 16, 2008, filed as Exhibit 99.1 to Form 8-K with the U.S. Securities and Exchange Commission on April 16, 2008.

I am signing this Declaration under penalty of perjury.

Dated: Wilmington, Delaware
May 13, 2008



Sean M. Brennecke (#4686)

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RELIANT PHARMACEUTICALS, INC., a Delaware Corporation,

Plaintiff,

v.

ABBOTT LABORATORIES, an Illinois corporation, and LABORATOIRES FOURNIER S.A., a French corporation,

Defendants.

Civil Action No. 04-350

COMPLAINT

Plaintiff, Reliant Pharmaceuticals, Inc. for its Complaint against defendants Abbott Laboratories and Laboratories Fournier S.A. (hereinafter "Defendants"), alleges as follows:

1. Plaintiff Reliant Pharmaceuticals, Inc. ("Reliant") is a Delaware Corporation having a principal place of business at 110 Allen Road, Liberty Corner, New Jersey 07938.

2. On information and belief, defendant Abbott Laboratories ("Abbott") is a corporation organized under the laws of the State of Illinois, having its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

3. On information and belief, defendant Laboratoires Fournier S.A. ("Fournier") is a French corporation having its principal place of business at 42 rue de Longvic, 21300 Chenôve, France, and a place of business in the United States of America, under the alter ego Fournier Pharma Corp., located at 6 Campus Drive, Parsippany, New Jersey, 07054.

JURISDICTION AND VENUE

4. This action for declaratory judgment arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.* and 21 U.S.C. § 355. Subject matter jurisdiction exists pursuant to

28 U.S.C. §§ 1331 and 1338(a), 35 U.S.C. § 271(e)(2) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This is a case of actual controversy within the Court's jurisdiction seeking a declaratory judgment of non-infringement, invalidity, and unenforceability of U.S. Patent Nos. 6,074,670 (the "'670 patent"), 6,277,405 (the "'405 patent"), 6,589,552 (the "'552 patent") and 6,652,881 (the "'881 patent").

5. Venue in this judicial district is proper pursuant to 28 U.S.C. §1391 and/or 1400(b). Personal jurisdiction over Defendants comports with the United States Constitution and Delaware's long-arm statute, 10 Del. C. § 3104. Defendants also have subjected themselves to the jurisdiction of this Court by, upon information and belief, commencing several related lawsuits in Delaware, including *Abbott Laboratories, et al., v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 02-1512 (MPT), and *Abbott Laboratories, et al. v. Impax Laboratories*, C.A. No. 03-120 (KAJ), alleging infringement of the same patents for which Plaintiff seeks a declaratory judgment of non-infringement, invalidity and unenforceability in this action.

BACKGROUND

6. On information and belief, Defendant Abbott Laboratories develops, manufactures and markets branded pharmaceutical products. Typically, branded drugs are those that are subject to approval by the United States Food and Drug Administration ("FDA") of a New Drug Application ("NDA"). Once approved, such products generally are referred to as "brand-name" or "branded" drugs because they are marketed under a trade name or trademark for the drug product, rather than the chemical name for the active pharmaceutical ingredient or "drug substance" in the drug product. Non-branded or generic drugs are typically marketed under the chemical name of the active pharmaceutical ingredient in the drug product.

7. Reliant is a privately held pharmaceutical company that exclusively markets branded pharmaceutical products to U.S.-based primary care and targeted specialty physicians.

The Hatch-Waxman Act

8. The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (1994) and 35 U.S.C. § 271(d)-(h) (1995), known as the Hatch-Waxman Act, was enacted in 1984. Section 505 of the Hatch-Waxman Act described three types of new drug applications: (a) an application that contains full reports of investigations of safety and effectiveness (an "NDA"); (b) an application that contains full reports of investigations of safety and effectiveness, but where at least some of the information required for approval comes from studies (i) not conducted by or for the applicant and (ii) for which the applicant has not obtained a right of reference (a "Section 505(b)(2) Application"); and (c) an application that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use to a previously-approved product (referred to as an Abbreviated New Drug Application or "ANDA").

9. This action arises out of Reliant's filing of a Section 505(b)(2) Application seeking FDA clearance to market a new drug product where some of the information required for approval comes from studies conducted by or for Abbott and for which Reliant has not obtained a right of reference from Abbott.

10. As a mechanism for resolving patent disputes, the Hatch-Waxman Act requires that the holder of each NDA and Section 505(b)(2) Application submit information about certain patents associated with its branded drug. In particular, brand-name drug manufacturers must file "the patent number and the expiration date of any patent which claims the drug for which the

applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. §355(b)(1).

11. The FDA lists the patent information, including each patent number and expiration date, provided by a brand-name drug manufacturer in a publication entitled, "Approved Drug Products with Therapeutic Equivalence Evaluations" (known throughout the industry as the "Orange Book").

12. Where a 505(b)(2) Application relies upon investigations of safety or efficacy that have been performed by or for the holder of a previously-approved NDA (as opposed to published literature), the applicant must address the Orange Book patent information for any "patent which claims the drug or drugs on which investigations that are relied upon by the applicant for approval of its application were conducted or which claims a use for such drug or drugs." 21 C.F.R. § 314.52(a). In particular, the Hatch-Waxman Act requires an applicant filing a Section 505(b)(2) Application to submit one of four patent certifications:

- a Paragraph I certification stating that no patent information has been filed for the approved drug;
- a Paragraph II certification stating that the patent has expired;
- a Paragraph III certification stating that the patent will expire on a certain date (and that the applicant does not seek approval before that date); or
- a Paragraph IV certification stating that the patent is invalid and/or will not be infringed.

21 U.S.C. § 355(b)(2)(A)(I)-(IV).

13. If a Section 505(b)(2) applicant files a "Paragraph IV" certification stating that it believes that an unexpired patent associated with the previously-approved drug product is invalid, unenforceable, and/or not infringed by its proposed new drug product, a statutory and regulatory framework governing the approval process is triggered. 21 U.S.C. § 355(b)(3); 21 C.F.R. § 314.52.

14. Applicants filing either a Section 505(b)(2) Application or ANDA must give a notice of the "Paragraph IV" certification to the patentee and owner of the NDA under which the corresponding branded product is sold. 21 U.S.C. § 355(b)(3)(A)-(B); 21 C.F.R. § 314.52(a)(1)-(2). That notice must include a detailed statement of the grounds for the belief that the patent is invalid, unenforceable, and/or not infringed. 21 U.S.C. § 355(b)(3)(D)(ii); 21 C.F.R. § 314.52(c)(6).

15. In order to facilitate the orderly resolution of disputes arising out of Paragraph IV certifications without requiring the FDA to make patent-related determinations of law or fact — issues that the FDA has acknowledged are outside the scope of its expertise — the Hatch-Waxman Act included special jurisdictional provisions to allow the federal courts to exercise case or controversy jurisdiction to rule on a Paragraph IV applicant's claims of patent invalidity, unenforceability, or non-infringement before any actual commercial manufacturing or sales of the proposed 505(b)(2) product take place. 35 U.S.C. § 271(e)(2).

16. The patentee may commence an infringement action against the 505(b)(2) applicant within 45 days from the date it receives notice of the Paragraph IV certification. 21 U.S.C. § 355(c)(3)(C). If the patentee brings suit within the 45-day period, the Hatch-Waxman Act prohibits the FDA from approving the 505(b)(2) application for a period of 30 months, unless the litigation is resolved earlier.

17. If a patent holder does not bring a Paragraph IV infringement action within 45 days, the FDA must generally make the approval of the 505(b)(2) application effective immediately upon satisfactory completion of its substantive review. 21 U.S.C. § 355(b)(3).

18. The Hatch-Waxman Act bars all parties from bringing a declaratory judgment action for patent invalidity, unenforceability, or non-infringement until after the expiration of the 45-day period following the patent-holder's receipt of notice of a Paragraph IV certification. 21 U.S.C. § 355(c)(3)(D)(I).

EXISTENCE OF CAUSE OF ACTION CONTROVERSY

19. Pharmaceutical products containing the drug substance fenofibrate are prescribed as a lipid and cholesterol lowering agent for adults with increased triglyceride levels. The drug substance fenofibrate is in the public domain and not protected by claims of any valid and existing patents.

20. Abbott currently sells a fenofibrate tablet product in the United States under the brand name Tricor®. Tricor® fenofibrate tablets were approved for sale by the FDA under NDA No. 21-203. On information and belief, Abbott listed at least five patents in the Orange Book with respect to NDA No. 21-203. They are United States Patent Nos. 4,895,726 (the "'726 patent"), the '670 patent, the '405 patent, the '552 patent and the '881 patent.

21. Fournier is the owner by assignment of the '670 patent, the '405 patent, the '552 patent and the '881 patent (collectively, the "Patents in Suit").

22. Upon information and belief, Abbott is the exclusive licensee in the United States of the Patents in Suit.

23. The Patents in Suit all claim fenofibrate dosage forms with specific formulation characteristics.

24. Abbott previously sold a capsule version of a fenofibrate product under the Tricor® brand name. Abbott's Tricor® fenofibrate capsules were approved for sale by the FDA under NDA No. 19-304. NDA No. 19-304 is listed in the Orange Book by the FDA as a "discontinued product," although generic versions of that product are currently approved for sale by the FDA.

25. The only patent listed in the Orange Book concerning NDA 19-304 is the '726 patent. The '726 patent claims fenofibrate formulations containing fenofibrate and a solid surfactant that have been "co-micronized" (defined by the inventors as "the micronization of an intimate mixture of fenofibrate and a solid surfactant") to increase the bioavailability of the product.

26. In February 2004, Reliant received notice from the FDA that the agency had accepted for filing Reliant's Section 505(b)(2) Application, NDA No. 21-695, seeking approval of a new fenofibrate capsule product preliminarily named "RP 1824." Reliant's Section 505(b)(2) Application for RP 1824 relies upon studies that were performed by or on behalf of Abbott to establish the safety and efficacy of Abbott's discontinued fenofibrate capsule product approved under NDA 19-304.

27. Reliant filed a Paragraph IV certification with respect to the '726 patent in its Section 505(b)(2) application, certifying that, to the best of Reliant's knowledge and belief, the importation, manufacture and sale of RP 1824 would not infringe the '726 patent. Reliant provided the requisite notice of its filing and Paragraph IV certification to Abbott and Fournier.

28. In Reliant's notice letter to Abbott and Fournier with respect to the '726 patent, Reliant offered to provide documents to Abbott and Fournier's outside counsel demonstrating

that RP 1824 would not infringe any of the claims of the '726 patent including an "offer of confidential access" to the 505(b)(2) Application pursuant to Section 355(b)(3)(D)(i)(III).

29. In response, by letter dated March 1, 2004, counsel for Abbott and Fournier rejected the terms of Reliant's offer for confidential access, arguing that Abbott and Fournier should not be limited in their confidential examination of Reliant's application solely to an analysis of the non-infringement of the '726 patent, and asserting that Abbott and Fournier would "only accept these samples and information under terms that allow us to use the samples and information to perform an infringement analysis with respect to any and all of Abbott's and Fournier's patent rights."

30. Abbott and Fournier reiterated this demand in another letter dated March 16, 2004, in which Abbott and Fournier stated that:

> Reliant's effort to prevent Abbott and Fournier from evaluating infringement under patents other than the '726 patent until *after* the 45-day period expires raises serious concerns on our part. It is impeding Abbott and Fournier's evaluation of infringement of the '726 patent by Reliant. What is more, it heightens our concern about the propriety of Reliant's decision to provide a Paragraph IV certification only with respect to the '726 patent (which is the patent listed in the *Orange Book* for Abbott's NDA 19-304) without providing a Paragraph IV certification with respect to the '670 patent; the 405 patent; the '552 patent; and the '881 patent, which are listed in the Orange Book for Abbott's NDA 21-203 along with the '726 patent. . . .
>
> In order for Abbott and Fournier to evaluate infringement for infringement [sic] of the patents that are listed in the Orange Book for NDA 21-203, we demand that Reliant produce the materials requested in my March 1, 2004 letter no later than Friday, March 19, 2004, under terms allowing Abbott and Fournier's outside counsel, in-house counsel (who are not involved in any competitive decision making role concerning fenofibrate), and outside independent experts access to the materials for the purpose of evaluating infringement of any of Abbott and Fournier's patent rights. If Reliant does not comply with this request, we reserve the right to seek appropriate recourse.

31. Abbott and Fournier reiterated their March 1 demand for samples of RP 1824 in a letter dated April 7, 2004. To date, Reliant has not provided such samples to Abbott and Fournier.

32. Abbott and Fournier's assertion that "[they] reserve the right to seek appropriate recourse" is a thinly-veiled threat that Abbott and Fournier will bring a patent infringement action against Reliant if Reliant fails to produce a sample of RP 1824 for Abbott's and Fournier's examination and comply with additional, litigation-minded demands.

33. Abbott and Fournier have already asserted the Patents in Suit against Cipher Pharmaceuticals Ltd., another filer of a Section 505(b)(2) application for a fenofibrate dosage form, in an action pending in the United States District Court for the District of Puerto Rico, Case No. 3:03-cv-01421 (DRD)(the "Cipher Litigation"). In the Cipher litigation, Abbott and Fournier assert the same patents as the Patents in Suit against another proposed Section 505(b)(2) fenofibrate product.

34. In late 2003, Cipher announced that Reliant would be the United States distributor of the proposed Cipher fenofibrate product. Subsequently, Abbott and Fournier served a subpoena dated March 3, 2004 on Reliant in connection with the Cipher Litigation, demanding, among other things, access to "all documents relating to fenofibrate products" in Reliant's possession, custody or control. This subpoena obviously calls for all documents relating to both the Cipher fenofibrate product as well as RP 1824, despite the fact that Abbott and Fournier are fully aware that the Cipher fenofibrate product is the subject of an entirely different Section 505(b)(2) application.

35. Abbott and Fournier have similarly asserted the Patents in Suit against at least four generic ANDA applicants: Teva Pharmaceuticals USA, Inc., Par Pharmaceutical, Inc., Impax Laboratories, and Ranbaxy Pharmaceuticals.

36. On information and belief, Abbott and Fournier intend to bring an action for infringement against Reliant with respect to the Patents in Suit in order to prevent the importation, manufacture, offer for sale, and sale of RP 1824, which would compete against Abbott's Tricor products in the United States market for fenofibrate dosage forms.

37. Abbott's and Fournier's conduct is sufficient to indicate their intent to enforce the Patents in Suit against Reliant.

38. Reliant has an objectively reasonable apprehension that Abbott and Fournier will sue Reliant to enforce the Patents in Suit.

THE PATENTS IN SUIT

The '670 Patent

39. The '670 patent, entitled "Fenofibrate Pharmaceutical Composition Having High Bioavailability and Method for Preparing it" issued on June 13, 2000 to Andre Stamm and Pawan Seth. Its owner by assignment is Fournier. On information and belief, Abbott is the exclusive licensee of the '670 patent. A true and correct copy of the '670 patent is attached hereto as Exhibit A.

40. The '670 patent contains 38 claims, only two of which (Claims 1 and 12) are independent. Claim 1 of the '670 patent recites:

> [a]n immediate-release fenofibrate composition comprising:
>
> (a) an inert hydrosoluble carrier covered with at least one layer containing fenofibrate in a micronized form having a size less than 20μm, a hydrophilic polymer and a surfactant; and

(b) optionally one or several out phase(s) or layer(s), wherein, based on the weight of (a), said inert hydrophilic carrier makes up from 20 to 50% by weight, said fenofibrate makes up from 20 to 45% by weight, said hydrophilic polymer makes up from 20 to 45% by weight, and said surfactant makes up from 0.1 to 3% by weight.

41. Similarly, Claim 12 recites an immediate release fenofibrate composition that includes polyvinylpyrrolidone ("PVP"), a specific type of hydrophilic polymer, which constitutes between 20% and 45% of the composition by weight.

42. Reliant's proposed RP 1824 product does not infringe any valid claim of the '670 patent.

The '405 Patent

43. The '405 patent entitled "Fenofibrate pharmaceutical composition having high bioavailability and method for preparing it" issued on August 21, 2001 to Andre Stamm and Pawan Seth. Its owner by assignment is Fournier. On information and belief, Abbott is the exclusive licensee of the '405 patent. A true and correct copy of the '405 patent is attached hereto as Exhibit B.

44. Claim 1 of the '405 patent, the sole independent claim, is as follows:

> A composition comprising a hydrosoluble carrier and micronized fenofibrate having a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or with 0.025M sodium lauryl sulfate.

Claims 2-13 depend from claim 1, either directly or indirectly.

45. Reliant's proposed RP 1824 product does not infringe any valid claim of the '405 patent.

The '552 Patent

46. The '552 patent entitled "Fenofibrate pharmaceutical composition having high bioavailability and method for preparing it" issued on July 8, 2003 to Andre Stamm and Pawan Seth. Its owner by assignment is Fournier. On information and belief, Abbott is the exclusive licensee of the '552 patent. A true and correct copy of the '552 patent is attached hereto as Exhibit C.

47. The '552 patent contains 57 claims, only three of which (Claims 1, 31 and 57) are independent. Claim 1 of the '552 patent is as follows:

> A fenofibrate composition comprising granulates, wherein the granulates comprise micronized fenofibrate having a particle size below 20 μm, inert hydrosoluble carrier particles and at least 20% by weight of at least one hydrophilic polymer, wherein the weight ratio of fenofibrate to hydrophilic polymer is from 1/10 to 4/1.

Claims 2-30 and 56 depend from claim 1, either directly or indirectly.

48. Similarly, claim 31 recites a fenofibrate composition where the hydrophilic polymer is polyvinylpyrrolidone. Claims 32-55 depend directly from claim 31.

49. Similarly, claim 57 recites a fenofibrate composition "wherein the weight ratio of surfactant to hydrophilic polymer is from 1/500 to 1/10."

50. Reliant's proposed RP 1824 product does not infringe any valid claim of the '552 patent.

The '881 Patent

51. The '881 patent entitled "Fenofibrate pharmaceutical composition having high bioavailability" issued on November 25, 2003 to Andre Stamm and Pawan Seth. Its owner by assignment is Fournier. On information and belief, Abbott is the exclusive licensee of the '881 patent. A true and correct copy of the '881 patent is attached hereto as Exhibit D.

52. The '881 patent contains 41 claims, only eight of which (Claims 1, 6, 11, 15, 22, 27, 32 and 37) are independent. Claim 1 of the '881 patent is as follows:

> A composition comprising micronized fenofibrate, wherein the composition has a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate.

Claims 2-5 depend directly from claim 1.

53. Similarly, claim 6 recites an orally administrable tablet comprising micronized fenofibrate. Claims 7-10 depend directly from claim 6.

54. Similarly, claim 11 recites a composition comprising micronized fenofibrate and at least one polymer. Claims 12-14 depend directly from claim 11.

55. Similarly, claim 15 recites composition comprising at least one inert carrier and one or more outer layers comprising micronized fenofibrate. Claims 16-21 depend directly from claim 15.

56. Similarly, claim 22 recites a composition comprising granulates which comprise micronized fenofibrate. Claims 23-26 depend directly from claim 22.

57. Similarly, claim 27 recites an orally administrable tablet comprising granulates, wherein the granulates comprise micronized fenofibrate. Claims 28-31 depend directly from claim 27.

58. Similarly, claim 32 recites an orally administrable capsule comprising granulates, wherein the granulates comprise micronized fenofibrate. Claims 33-36 depend directly from claim 32.

59. Similarly, claim 37 recites a granulate comprising micronized fenofibrate. Claims 38-41 depend directly from claim 37.

60. Reliant's proposed RP 1824 product does not infringe any valid claim of the '881 patent.

FIRST CAUSE OF ACTION

Declaratory Judgment of Non-Infringement and Invalidity of United States Patent No. 6,074,670

61. Reliant repeats and realleges the allegations of paragraphs 1-60 above.

62. An actual controversy exists between Reliant and Abbott under 35 U.S.C. § 271(e)(2) with respect to the '670 patent because Abbott and Fournier have (a) represented to Reliant that Reliant should have filed a Paragraph IV certification with respect to the '670 patent; (b) implicitly threatened to commence an action for infringement against Reliant unless Reliant produces samples of RP 1824 for Abbott's and Fournier's examination; (c) commenced an action against Cipher Pharmaceuticals under the same patents and with respect to a fenofibrate product; (d) demanded copies of documents relating to RP 1824 in the Cipher Litigation; and (e) commenced actions for infringement of the Patents in Suit against several generic ANDA applicants. Reliant, therefore, has a reasonable apprehension that Abbott and Fournier will sue Reliant to enforce the Patents in Suit.

63. Reliant's NDA No. 21-695 for RP 1824 does not seek FDA approval for a pharmaceutical composition that infringes any valid claim of the '670 patent.

64. The '670 patent is invalid in that it fails to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

SECOND CAUSE OF ACTION

Declaratory Judgment of Non-Infringement and Invalidity of United States Patent No. 6,277,405

65. Reliant repeats and realleges the allegations of paragraphs 1-64 above.

66. An actual controversy exists between Reliant and Abbott under 35 U.S.C. § 271(e)(2) with respect to the '405 patent because Abbott and Fournier have (a) represented to Reliant that Reliant should have filed a Paragraph IV certification with respect to the '405 patent; (b) implicitly threatened to commence an action for infringement against Reliant unless Reliant produces samples of RP 1824 for Abbott's and Fournier's examination; (c) commenced an action against Cipher Pharmaceuticals under the same patents and with respect to another fenofibrate product; (d) demanded copies of documents relating to RP 1824 in the Cipher Litigation; and (e) commenced actions for infringement of the Patents in Suit against several generic ANDA applicants.

67. Reliant's NDA No. 21-695 for RP 1824 does not seek FDA approval for a pharmaceutical composition that infringes any valid claim of the '405 patent.

68. The '405 patent is invalid in that it fails to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

THIRD CAUSE OF ACTION

Declaratory Judgment of Non-Infringement and Invalidity of United States Patent No. 6,589,552

69. Reliant repeats and realleges the allegations of paragraphs 1-68 above.

70. An actual controversy exists between Reliant and Abbott under 35 U.S.C. § 271(e)(2) with respect to the '552 patent because Abbott and Fournier have (a) represented to Reliant that Reliant should have filed a Paragraph IV certification with respect to the '552 patent;

(b) implicitly threatened to commence an action for infringement against Reliant unless Reliant produces samples of RP 1824 for Abbott's and Fournier's examination; (c) commenced an action against Cipher Pharmaceuticals under the same patents and with respect to another fenofibrate product; (d) demanded copies of documents relating to RP 1824 in the Cipher Litigation; and (e) commenced actions for infringement of the Patents in Suit against several generic ANDA applicants. Reliant, therefore, has a reasonable apprehension that Abbott and Fournier will sue Reliant to enforce the Patents in Suit.

71. Reliant's NDA No. 21-695 for RP 1824 does not seek FDA approval for a pharmaceutical composition that infringes any valid claim of the '552 patent.

72. The '552 patent is invalid in that it fails to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

FOURTH CAUSE OF ACTION

Declaratory Judgment of Non-Infringement and Invalidity of United States Patent No. 6,652,881

73. Reliant repeats and realleges the allegations of paragraphs 1-72 above.

74. An actual controversy exists between Reliant and Abbott under 35 U.S.C. § 271(e)(2) with respect to the '881 patent because Abbott and Fournier have (a) represented to Reliant that Reliant should have filed a Paragraph IV certification with respect to the '881 patent; (b) implicitly threatened to commence an action for infringement against Reliant unless Reliant produces samples of RP 1824 for Abbott's and Fournier's examination; (c) commenced an action against Cipher Pharmaceuticals under the same patents and with respect to another fenofibrate product; (d) demanded copies of documents relating to RP 1824 in the Cipher Litigation; and (e) commenced actions for infringement of the Patents in Suit against several generic ANDA

applicants. Reliant, therefore, has a reasonable apprehension that Abbott and Fournier will sue Reliant to enforce the Patents in Suit.

75. Reliant's NDA No. 21-695 for RP 1824 does not seek FDA approval for a pharmaceutical composition that infringes any valid claim of the '881 patent.

76. The '881 patent is invalid in that it fails to comply with one or more of the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

FIFTH CAUSE OF ACTION

Declaratory Judgment of Unenforceability as to all Patents in Suit

77. Reliant repeats and realleges the allegations of paragraphs 1-76 above.

78. An actual controversy exists between Reliant and Abbott under 35 U.S.C. § 271(e)(2) with respect to the Patents in Suit because Abbott and Fournier have (a) represented to Reliant that Reliant should have filed a Paragraph IV certification with respect to the Patents in Suit; (b) implicitly threatened to commence an action for infringement against Reliant unless Reliant produces samples of RP 1824 for Abbott's and Fournier's examination; (c) commenced an action against Cipher Pharmaceuticals under the same patents and with respect to another fenofibrate product; (d) demanded copies of documents relating to RP 1824 in the Cipher Litigation; and (e) commenced actions for infringement of the Patents in Suit against several generic ANDA applicants. Reliant, therefore, has a reasonable apprehension that Abbott and Fournier will sue Reliant to enforce the Patents in Suit.

79. The '670 patent, the '405 patent, the '552 patent and the '881 patent are unenforceable due to inequitable conduct by the inventors before the United States Patent and Trademark Office. The specifications for each of those patents misrepresent the dissolution profile for a prior art product known as Lipanthyl 200M. Specifically, Figures 1 and 2 in each of

these patents compares the dissolution profiles for the alleged invention to that of the prior art Lipanthyl 200M. The inventors, with the intent to deceive the PTO, misrepresented the dissolution profile for Lipanthyl 200M and furthermore misrepresented that the dissolution profile for the alleged invention was "distinctly better" than that for Lipanthyl 200M.

80. In addition, during the prosecution of at least the '670 patent, the '405 patent, and the '881 patent, the inventors, with intent to deceive the PTO, overcame the Patent Examiner's rejections of certain claims by misrepresenting the dissolution profile for Lipanthyl 200M in the following documents:

a. Response and Amendment under 37 C.F.R. § 1.111, dated December 4, 1998, during prosecution of the application that became the '670 patent;

b. Response and Amendment under 37 C.F.R. § 1.111, dated May 20, 1999, during prosecution of the application that became the '670 patent;

c. Reply under 37 C.F.R. § 1.111, dated November 17, 1999, during prosecution of the application that became the '670 patent;

d. Request for Reconsideration under 37 C.F.R. § 1.111, dated June 25, 2003, during prosecution of the application that became the '881 patent ; and

e. Response and Amendment under 37 C.F.R. § 1.111, dated January 26, 2001, during prosecution of the application that became the '405 patent .

81. The '552 patent is intimately related to the '670 patent, the '405 patent, and the '881 patent because it is a continuation of the other three patents and furthermore has the same subject matter, the same inventors, the same specification, and relies on the same misrepresented prior art. The inventors' broad pattern of inequitable conduct before the United States Patent and

Trademark Office in their prosecution of the '670 patent, the '405 patent, and the '881 patent has tainted the '552 patent so as to render it unenforceable.

82. The '670 patent, the '405 patent, the '881 patent, and the '552 patent are intimately related to each other because the latter three are continuations of the '670 patent and furthermore each patent has the same subject matter, the same inventors, the same specification, and relies on the same misrepresented prior art. The inventors' inequitable conduct before the United States Patent and Trademark Office in their prosecution of each of the '670 patent, the '405 patent, the '881 patent and the '552 patent has tainted the other three so as to render them unenforceable.

REQUEST FOR RELIEF

WHEREFORE, Reliant respectfully requests that this Court enter judgment:

(a) declaring that Reliant's fenofibrate product described in NDA No. 21-695 does not infringe any valid and enforceable claim of United States Patent Nos. 6,074,670, 6,277,405, 6,589,552 or 6,652,881;

(b) declaring that United States Patent Nos. 6,074,670, 6,277,405, 6,589,552 and 6,652,881 are unenforceable due to inequitable conduct before the United States Patent and Trademark Office;

(c) awarding Reliant its reasonable costs and attorneys' fees in connection with this action; and

(d) awarding Reliant such other and further relief as this Court deems just and proper.

POTTER ANDERSON & CORROON LLP

OF COUNSEL:

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Edward DeFranco
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Dated: June 1, 2004
634135

BY: _____
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Attorneys for Plaintiff
Reliant Pharmaceuticals, Inc.

EXHIBIT B

Reliant Pharmaceuticals/Inc · S-1/A · On 8/5/05 · EX-10.29

Filed On 8/5/05 4:44pm ET · SEC File 333-125127 · Accession Number 1193125-5-159168

As Of	*Filer*	*Filing*	*As/For/On*	*Docs:Pgs*
8/05/05	Reliant Pharmaceuticals/Inc	**S-1/A**		20:724

Pre-Effective Amendment to Registration Statement (General Form) · Form S-1
Filing Table of Contents

EX-10.29 · Development, License and Supply Agreement, Dated as of May 7, 2001

Development, License and Supply Agreement, dated as of May 7, 2001

Exhibit 10.29

CONFIDENTIAL **EXECUTION COPY**

DEVELOPMENT,
LICENSE AND SUPPLY AGREEMENT

dated as of May 7, 2001

among

ETHYPHARM, S.A.
194 Bureaux de la Colline
92213 Saint Cloud
France

and

ETHYPHARM INDUSTRIES, S.A.
194 Bureaux de la Colline
92213 Saint Cloud
France

and

RELIANT PHARMACEUTICALS, LLC
110 Allen Road
Liberty Corner, New Jersey 07938
United States

CONFIDENTIAL

THIS DEVELOPMENT, LICENSE AND SUPPLY AGREEMENT, dated as of May 7, 2001, by and among ETHYPHARM S.A., a corporation organized under the laws of France, with its principal offices at 194 Bureaux de la Colline, 92213 Saint Cloud, France, ETHYPHARM INDUSTRIES S.A., a corporation organized under the laws of France, with its principal offices at 194 Bureaux de la Colline, 92213 Saint Cloud, France (Ethypharm, S.A., Ethypharm Industries, S.A., together with their respective subsidiaries and Affiliates, collectively, "ETHYPHARM"), and RELIANT PHARMACEUTICALS, LLC, a limited liability company organized under the laws of the State of Delaware, with its principal offices at 110 Allen Road, Liberty Corner, New Jersey 07938, United States of America ("RELIANT"). Capitalized terms used herein without definition shall have the meanings specified in Section 1 hereof.

WITNESSETH THAT:

WHEREAS, ETHYPHARM is engaged in the development of new formulations of pharmaceutical specialties and, in particular, is the owner of, and has the right to grant licenses with respect to, certain Know-How and Intellectual Property (as hereinafter defined) used in connection with the development, formulation, manufacture, encapsulation, packaging and otherwise related to the Product (as hereinafter defined);

WHEREAS, ETHYPHARM wishes to grant to RELIANT an exclusive license, with the right to sublicense, to such Intellectual Property in the Territory (as hereinafter defined) in relation with the Product developed by ETHYPHARM, and RELIANT is willing to accept such a license on the terms and conditions set forth hereinafter; and

WHEREAS, the parties desire to set forth herein, among other things, certain agreements regarding the product development, supply and manufacturing obligations of

Initials: _____

ETHYPHARM to RELIANT in respect of the Product and the clinical development, licensing, purchasing and marketing obligations of RELIANT to ETHYPHARM in respect of the Product, Intellectual Property and Know-How.

NOW, THEREFORE, in consideration of the agreements and covenants hereinafter set forth and intending to be legally bound hereby, the parties hereto covenant and agree as follows:

1. **DEFINITIONS**

1.1 "Act" shall mean the United States Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq*., and the regulations promulgated thereunder, in each case as hereafter amended from time to time, and similar legislation in other countries of the Territory.

1.2 "Additional Manufacturing Facility" shall have the meaning specified in Section 5.4.

1.3 "Affiliate" means, with respect to any Person, any other Person directly or indirectly controlling, controlled by, or under common control with, such other Person. For purposes hereof, the term "controlling" (including the terms "controlled by" and "under common control with"), as used with respect to any Person, will mean the direct or indirect ability or power to direct or cause the direction of management policies of such Person or otherwise direct the affairs of such Person, whether through ownership of at least fifty percent (50%) of the voting securities of such Person, by contract or otherwise. In addition and not in limitation of the foregoing, the following entities shall be deemed Affiliates of RELIANT: (i) PharmBay Investors, LLC; (ii) Bay City Capital Fund II, L.P.; and (iii) any of the lineal descendants of Nicholas J. Pritzker, deceased, trusts

primarily for the benefit of such lineal descendants, entities controlled by such lineal descendants and/or trust for their benefit.

1.4 "API" or "Active Pharmaceutical Ingredient" means the raw non-micronized fenofibrate used in the Product manufactured by a party other than ETHYPHARM or any of its Affiliates.

1.5 "Applicable Laws" means all laws, statutes, codes, treaties, ordinances, judgments, decrees, directives, injunctions, orders of any court, arbitrator or Governmental Authority, rules, regulations, interpretations, authorizations and Applicable Permits of any Governmental Authority applicable to any of the parties hereto, the transactions contemplated hereby and/or the Product.

1.6 "Applicable Permits" means any waiver, exemption, variance, permit, license, authorization, consent, certification, registration or similar approval (including, without limitation, any NDA), including, without limitation, product registrations by or of any Governmental Authority required to be obtained or maintained under Applicable Laws in connection with the formulation, development, registration, manufacture, packaging, labeling, import, export, shipment, receipt, storage, use, pricing or sale of the Product, regardless of the formulation or dosage form thereof, and any ingredient thereof.

1.7 "Approval Date" means, with respect to a particular country in the Territory, the date on which all Applicable Permits necessary for the commercial sale and pricing of the Product by or on behalf of RELIANT in such country have been issued and are in effect.

1.8 "Audit" shall have the meaning specified in Section 7.7.

1.9 "Bulk Product Form" shall mean the Product in such form which is ready for incorporation by or on behalf of RELIANT into Finished Dosage Form or such other form as may be sold commercially by RELIANT in the Territory.

1.10 "Business Day" means any day except Saturday, Sunday and any day which shall be a federal legal holiday in the United States or a day on which banking institutions in the State of New Jersey or Paris, France are authorized or required by law or other government action to close.

1.11 "cGMP" shall mean current Good Manufacturing Practices as in effect under the Act from time to time and similar regulations in other countries under Applicable Laws.

1.12 "CMC" shall mean the Chemistry and Manufacturing Controls section of the IND or NDA, as applicable, as then in effect.

1.13 "Combination Product" shall have the meaning specified in Section 6.10.

1.14 "Competing Dosage Form" shall mean a fenofibrate monotherapy product marketed by or on behalf of RELIANT other than the Product in a formulation and dosage form that is substantially similar or identical to the Product. For the purposes of this Agreement, no Combination Product shall be considered a Competing Dosage Form.

1.15 "Confidential Information" means, with respect to any Person (including, without limitation, the parties hereto), all proprietary or confidential information of such Person (including such Person's Affiliates and subsidiaries), including, without limitation, any non-public Intellectual Property, Know-How, financial information, procurement requirements, purchasing, manufacturing, customer or supplier information, business forecasts and plans, financing information, detailing, sales and merchandising, and marketing plans and information, pricing,

and accounting policies and procedures of or related to such Person; *provided*, *however*, that Confidential Information shall not include and information that (a) was or becomes generally available to the public other than as a result of an unauthorized disclosure by a party hereto or any of such party's subsidiaries, Affiliates, employees, agents or representatives; (b) was or becomes available to a party hereto on a non-confidential basis from a source other than (in the case of future information) any other party hereto (or any of such party's subsidiaries, Affiliates, employees, agents or representatives), provided that such source was not known be bound by any agreement to keep such information confidential or otherwise prohibited from transmitting the information by a contractual, legal or fiduciary obligation; or (c) is independently developed by any party hereto without the use of or reference to the Confidential Information of the other party hereto or any of such other party's subsidiaries or Affiliates.

1.16 "Contract Manufacturing Agreement" shall have the meaning specified in Section 5.5.

1.17 "Delivery Forecast" shall have the meaning specified in Section 7.4.

1.18 "DMF" shall mean the Drug Master File (together with all subsequent submissions, supplements and amendments thereto, and any materials, documents or information referred to or relied upon thereby) in the United States and any similar files in other countries of the Territory that relate to the Product.

1.19 "ETHYPHARM" shall have the meaning specified in the Preamble.

1.20 "ETHYPHARM Indemnified Claims" shall have the meaning specified in Section 6.4.

1.21 "ETHYPHARM Indemnified Parties" shall have the meaning specified in Section 13.2.

1.22 "ETHYPHARM Infringement Indemnitees" shall have the meaning specified in Section 6.5.

1.23 "Event of Default" shall have the meaning specified in Section 12.1.

1.24 "Exception Notice" shall have the meaning specified in Section 7.6.

1.25 "FDA" shall mean the Food and Drug Administration in the United States and similar Governmental Authorities in other countries within the Territory, including any successor agencies performing comparable functions.

1.26 "Finished Dosage Form" means the Product in the form of single dose capsules containing the formulation and dosage of API as developed by ETHYPHARM and such quantity and type of excipients specified in the Specifications, which shall be labeled and packaged (in high density polyethylene (HDPE) bottles and/or blister packs as specified by RELIANT) such that it is ready for immediate marketing, sale or other distribution by RELIANT.

1.27 "Governmental Authority" means any international, national, domestic, foreign, regional, local or other governmental or regulatory body, agency, authority, court or other authorized Person, including, without limitation, all such Persons having jurisdiction over the formulation, development, registration, manufacture, packaging, labeling, import, export, shipment, storage, use, pricing or sale of the Product, regardless of the formulation or dosage form thereof, or health and safety matters generally.

1.28 "IND" shall mean an Investigational New Drug Application under the Act (together with all subsequent submissions, supplements and amendments thereto,

and any materials, documents or information referred to or relied upon thereby) seeking authorization to commence clinical trials of the Product in humans, and similar applications or filings in the other countries within the Territory.

1.29 "Initial Term" shall have the meaning specified in Section 11.1.

1.30 "Intellectual Property" shall mean all patents (including, without limitation, the Patents), copyrights, trademarks, service marks, service names, trade names, internet domain names, e-mail addresses, applications or registrations for any of the foregoing, or extensions, renewals, continuations or re-issues thereof, or amendments or modifications thereto, brandmarks, brand names, trade dress, labels, logos, know-how (including, without limitation, the Know-How), show-how, technical and non-technical information, trade secrets, formulae, techniques, sketches, drawings, models, inventions, designs, specifications, processes, apparatus, equipment, databases, research, experimental work, development, pharmacology and clinical data, software programs and applications, software source documents, third-party licenses, and any similar type of proprietary intellectual property right vesting in the owner and/or licensee thereof pursuant to the applicable laws or regulations of any relevant jurisdiction or under any applicable license or contract, whether now existing or hereafter created, together with all modifications, enhancements and improvements thereto.

1.31 "Know-How" means any and all proprietary methods, devices, technology, trade secrets, inventions, compositions, designs, formulae, know-how, show-how, technical and training manuals and documentation and other information, including, without limitation, processes and analytical methodologies used in

development, testing, analysis and manufacture, and medical, clinical and toxicological testing as well as other scientific data of ETHYPHARM, which is related to or used in connection with the Product or any ingredient thereof, and/or the formulation, development, registration, manufacture, packaging, labeling, import, export, receipt, shipment, storage, use, pricing or sale thereof, whether now known or hereafter developed.

1.32 "Launch Date" shall mean, with respect to each country in the Territory, the first date RELIANT receives proceeds from the commercial sale of the Product in such country.

1.33 "License" shall have the meaning specified in Section 3.1.

1.34 "License Exclusion Transaction" shall have the meaning specified in Section 3.1.

1.35 "LET Notice" shall have the meaning specified in Section 3.2.

1.36 "Make-Whole Payment" shall have the meaning specified in Section 3.4.

1.37 "Minimum Annual Sales" shall have the meaning specified in Section 3.4.

1.38 "NDA" shall mean any New Drug Application under the Act (together with all subsequent submissions, supplements and amendments thereto, and any materials, documents or information referred to or relied upon thereby) seeking approval to market, sell or otherwise distribute the Product, in any formulation or dosage form, in the United States, and similar applications or filings in the countries within the Territory.

1.39 "Net Royalties" means royalties payable to ETHYPHARM pursuant to the terms of this Agreement, net of any Taxes required to be withheld therefrom.

1.40 "Net Sales" means the aggregate amounts invoiced by RELIANT for sales of the Product produced using ETHYPHARM Intellectual Property to independent and

unrelated third-parties in the Territory, less any and all (a) trade, quantity and cash discounts; (b) commissions, discounts, refunds, rebates, chargebacks, retroactive price adjustments and any other allowances which effectively reduce the net selling price; (c) returns, bad debts and uncollectible accounts; (d) Taxes collected, charged or otherwise required to be paid by RELIANT in respect thereof; and (e) insurance, freight, warehousing and other transportation and storage costs related to shipment of the Product.

1.41 "Nonparticipating Party" shall have the meaning specified in Section 6.8.

1.42 "Patents" shall mean any issued patents and patent applications (including, without limitation, any applications or registrations therefor, extensions, renewals, continuations or re-issues thereof, or amendments or modifications thereto) that are currently owned or hereafter acquired or applied for by ETHYPHARM, which would be infringed by the formulation, development, registration, manufacture, packaging, labeling, import, export, receipt, shipment, storage, use, pricing or sale of the Product or any ingredient thereof in the Territory, but for the rights granted to RELIANT by ETHYPHARM under this Agreement, including but not limited to those patents and patent applications set forth on Schedule 1.42 attached hereto (as may such schedule shall be amended from time to time).

1.43 "Person" means any individual, partnership, association, joint venture, corporation, limited liability company, trust or Governmental Authority or other entity.

1.44 "Product" means a product composed of or containing micronized fenofibrate, in any dosage form, including encapsulated or bulk beads, granules or similar

presentations, including, without limitation, the fenofibrate product developed by ETHYPHARM for RELIANT pursuant to this Agreement and the Product Development Program.

1.45 "Product Development Program" shall have the meaning specified in Section 2.1.

1.46 "Recall" shall have the meaning specified in Section 7.9.

1.47 "Regulatory Applications" shall have the meaning specified in Section 2.4.

1.48 "RELIANT" shall have the meaning specified in the Preamble.

1.49 "RELIANT Clinical Data" shall have the meaning specified in Section 2.2.

1.50 "RELIANT Indemnified Claims" shall have the meaning specified in Section 6.5.

1.51 "RELIANT Indemnified Parties" shall have the meaning specified in Section 13.1.

1.52 "RELIANT Infringement Indemnitees" shall have the meaning specified in Section 6.4.

1.53 "Specifications" means the pharmaceutical formulation, manufacture, delivery, packaging, labeling, import, export, storage, receipt and shipment specifications for the Product (including Product in Bulk Product Form and Finished Dosage Form) and any excipients set forth on Exhibit A attached hereto (which Exhibit A may be amended or changed from time to time upon the agreement of the parties).

1.54 "Tax(es)" means, with respect to any Person, all federal, state, local, county, foreign and other taxes, assessments or other government charges, including, without limitation, income, estimated income, gross receipts, profits, business, license, occupation, franchise, capital stock, real or personal property, sales use, transfer, value added, employment or unemployment, social security, disability,

alternative or add-on minimum, customs, duty, excise, stamp, environmental or withholding taxes, including interest, penalties and additions in connection therewith for which such Person may be liable (including any such tax related to any other Person for which such Person is liable, by contract, as transferee or successor, by law, treaty or otherwise).

1.55 "Term" shall have the meaning specified in Section 11.1.

1.56 "Territory" means: (a) the United States of America, its territories and possessions including without limitation, Puerto Rico; (b) the Caribbean (including, without limitation, The Bahamas); (c) Mexico; and (d) Canada.

1.57 "Third Party Infringement" shall have the meaning specified in Section 6.8.

2. **PRODUCT DEVELOPMENT PROGRAM; CLINICAL DATA; PRODUCT REGISTRATION**

2.1 Product Development Program; Dosages. During the Term of this Agreement, ETHYPHARM and RELIANT shall develop the Product consistent with the terms of this Agreement in accordance with product development program set forth on Exhibit B attached hereto (the "Product Development Program"), which Exhibit B specifies the proposed development timetable and each party's respective responsibilities related to the development of the Product for sale in the Territory, including, without limitation, the preparation and filing of an NDA and the conduct of clinical trials related to the Product. As part of the Product Development Program, RELIANT shall establish a highest dosage (currently anticipated to be between 120mg and 200mg of API per capsule), however, RELIANT, at its option, may develop in collaboration with ETHYPHARM and conduct clinical trials in respect of other formulations and/or dosage forms of the Product. ETHYPHARM shall develop the formulations and dosage forms of the Product and manufacture the Product in

such formulations and dosage forms as shall be requested by RELIANT or otherwise required to comply with the Act and any applicable NDA and in compliance with the Product Development Program.

2.2 Ownership of Clinical Data. Subject to the provisions of Section 2.3, all preclinical, clinical, technical and other information relative to the clinical program, data, analyses, studies or similar information (including, without limitation, all Intellectual Property) generated or developed by or on behalf of the parties after the date hereof as a result of or in connection with the Product Development Program and the clinical trials conducted by RELIANT hereunder and thereunder (collectively, the "RELIANT Clinical Data"), shall be owned exclusively by RELIANT.

2.3 ETHYPHARM's Right to RELIANT Clinical Data. The parties agree, that following the issuance of an NDA for the purpose of licensing the Product and subject to the terms and conditions of this Agreement, ETHYPHARM shall have access to the RELIANT Clinical Data for use outside the Territory on the basis of terms and conditions to be negotiated in good faith between the parties; *provided*, *however*, as consideration for providing ETHYPHARM access to such RELIANT Clinical Data, such terms and conditions shall provide that RELIANT shall be entitled to receive [***] percent ([***]%) of any non-refundable license, royalty, fee and/or milestone payment received by, ETHYPHARM by or from any third party licensee of the Product. For the avoidance of doubt, the parties acknowledge and agree that ETHYPHARM shall have no rights in or to any RELIANT Clinical Data until the issuance of the final NDA or in the event that that the NDA is

[***]:Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

revoked, cancelled, withdrawn or otherwise impaired as a result of any act or omission by or behalf of ETHYPHARM of the types described in Section 4.4.

2.4 Regulatory Applications and Related Filings. Provided that ETHYPHARM satisfies its obligations under Section 2.5 and the Product Development Program in a timely manner, RELIANT shall exercise its commercially reasonable efforts to prepare, file and prosecute all necessary applications, submissions and regulatory filings (together with all documentation, correspondence and other supporting materials related thereto, collectively, the "Regulatory Applications") to obtain any Applicable Permits required to market the Product in the United States promptly following completion of the Product Development Program and in any event within a maximum period of six (6) months from completion of the Product Development Program. Upon the completion of those portions of the Product Development Program applicable to Canada and Mexico, RELIANT shall use its commercially reasonable efforts to file Regulatory Applications in those countries and in any event within a maximum period of six (6) months from completion of those portions of the Product Development Program applicable to these countries of the Territory. All Regulatory Applications shall be filed and submitted in RELIANT's name and shall be owned exclusively by RELIANT, and all Applicable Permits issued pursuant thereto shall be in the name of and owned exclusively by RELIANT. RELIANT shall be responsible for obtaining any and all necessary regulatory approvals from any Governmental Authority under any Applicable Law or Applicable Permit as a result of any changes to the Specifications requested by RELIANT and for reporting any such modifications to the Specifications to the

applicable Governmental Authority as appropriate. In the event that the submission of the Regulatory Applications does not take place within the time periods specified in this Section 2.4 as a result of RELIANT's breach of this Agreement or other refusal to submit such Regulatory Applications, then ETHYPHARM, as its sole remedy hereunder, may, upon at least sixty (60) days prior written notice to RELIANT, convert the exclusive license granted to RELIANT pursuant to Section 3.1 to a non-exclusive license solely in that country of the Territory where RELIANT failed to submit such Regulatory Application; *provided, however*, that RELIANT shall have the option, but not the obligation, for a period not to exceed eighteen (18) months to make an additional payment of $3,000 per day with respect to the United States ($300 per day with respect to each of Canada and Mexico), payable monthly in arrears, in which case ETHYPHARM shall not have the right to convert the License to a non-exclusive license in said country (it being agreed that such payments shall be made until such time as the Regulatory Application is submitted for the country in question).

2.5 ETHYPHARM's Development Responsibilities. Notwithstanding RELIANT's obligations under Section 2.4 to the contrary, ETHYPHARM shall prepare and deliver, and shall cause each applicable supplier or other third party (other than RELIANT) involved with the manufacture and packaging of the Product to prepare and deliver, to RELIANT and, as applicable, file or cause to be filed with the appropriate Governmental Authority: (a) the DMF, which shall be filed with FDA for the manufacture of the Product; and (b) the CMC section of the IND and the NDA, all of which shall be in accurate and complete, and in form and substance reasonably satisfactory to RELIANT and suitable for inclusion in the applicable filing. ETHYPHARM shall, at its own cost, cooperate with and assist RELIANT in the preparation, filing and prosecution of the Regulatory Applications, and shall prepare and deliver such other documents, and take such other actions, as may be necessary or appropriate to apply for, prosecute or obtain any Applicable Permits. All materials to be prepared by or on behalf of ETHYPHARM hereunder shall be prepared and delivered and, as applicable, filed, in timely manner in accordance with timetable established by the parties

hereunder. ETHYPHARM shall provide RELIANT with sufficient opportunity to review and comment upon all Regulatory Applications or portions thereof prepared by or on behalf of ETHYPHARM prior to their submission to any Governmental Authority. In the event that RELIANT requests any modifications to the Regulatory Applications or portions thereof required to be prepared by ETHYPHARM hereunder, the parties shall discuss such modifications in good faith; *provided, however*, that the party in whose name the Regulatory Application is being made shall retain the ultimate right to determine the contents thereof. In connection with this Agreement, ETHYPHARM shall also provide RELIANT with full access to all of its information and records, including, without limitation, its Intellectual Property and Confidential Information, related to the Product and its formulation, manufacture and packaging (including, without limitation, formulation, development, pharmacology and clinical data regarding the Product, any ingredient thereof (including fenofibrate)) in order that RELIANT may obtain and maintain the Applicable Permits contemplated by this Agreement and comply with Applicable Law.

2.6 Compliance of Specifications. The Specifications shall at all times be in compliance with the requirements of the Act and, in particular, an NDA applicable to the Product, such that RELIANT shall be entitled to market, sell and distribute the Product in the Territory, and the parties agree to make any changes to the Specifications as may be required to ensure such compliance.

3. **GRANT OF LICENSE**

3.1 Grant of License; License Exclusion. Subject to the terms set forth herein and in consideration for the payments set forth in Sections 4, 8 and 9 hereof,

ETHYPHARM hereby grants to RELIANT the exclusive (even as to ETHYPHARM) royalty-bearing license to all of ETHYPHARM's Intellectual Property related to the Product to make or have made (except to make or have made the Product in Bulk Product Form), develop, import, export, within the Territory, use, distribute, promote, market, sell and otherwise fully exploit the Product, in whatever formulation or dosage form, within the Territory (the "License"); *provided, however*, that the License shall not prevent ETHYPHARM from developing, manufacturing, licensing, promoting and marketing other products containing fenofibrate as the main active pharmaceutical ingredient in the form of microgranules, directly or through third parties, provided that fenofibrate is combined with another active pharmaceutical ingredient which does not belong to the statin family and for which there is no valid patent in the Territory (a "License Exclusion Transaction").

3.2 RELIANT Right of First Refusal Regarding License Exclusion Transactions. In the event that ETHYPHARM desires to enter into or consummate a License Exclusion Transaction, ETHYPHARM agrees that it shall first provide RELIANT with at least sixty (60) days prior written notice of such proposed Licensed Exclusion Transaction specifying the terms and conditions of the proposed product, product specifications, manufacturing specifications, product development program, license and royalty arrangement and marketing strategy related thereto (each, a "LET Notice"). Following delivery of any LET Notice, ETHYPHARM shall provide RELIANT with such information as RELIANT may reasonably request in order to allow RELIANT to evaluate the proposed License Exclusion Transaction described therein. Within sixty (60) days following its receipt of the LET Notice, RELIANT shall have the right, but not the obligation, upon delivery of written notice to ETHYPHARM to agree to enter into the transaction described by the LET Notice upon the terms and conditions stated therein. In the event that RELIANT notifies ETHYPHARM in writing that it does not wish to exercise its rights under this Section 3.2 or fails to respond to such LET Notice within such sixty (60) day period,

ETHYPHARM shall be free to enter into the License Exclusion Transaction described therein with a third party; *provided, however*, that ETHYPHARM may not offer to such third party any terms or conditions more favorable to such third party than those described in the LET Notice without first re-offering such opportunity to RELIANT pursuant to this Section 3.2; *provided, further*, that in the event ETHYPHARM shall not have entered into a binding agreement with such third party within one hundred eighty (180) days following the date of the LET Notice, ETHYPHARM shall not enter into or consummate such License Exclusion Transaction without re-offering such opportunity to RELIANT pursuant to this Section 3.2.

3.3 Sublicenses. RELIANT shall have the right to sublicense any and all of the rights granted pursuant to this Agreement, in whole or in part, to one or more Persons; *provided, however*, that RELIANT shall promptly (a) advise ETHYPHARM of the identity of any such sublicensee; and (b) provide ETHYPHARM with a copy of the sublicense agreement to establish that such sublicensee has been informed of the obligations under this Agreement. Notwithstanding the foregoing, RELIANT shall not be required to disclose to ETHYPHARM the amount or structure of any royalty or other payments due to RELIANT from any such sublicensees. RELIANT agrees that it shall require any sublicensees of any of its rights hereunder to preserve the confidentiality of any ETHYPHARM Intellectual Property or Confidential Information to the extent RELIANT is required to do so under this Agreement.

3.4 Minimum Annual Sales Requirement; Conversion to Non-Exclusive License. In order to maintain exclusivity of the License granted in Section 3.1, RELIANT shall be required to reach minimum annual sales of capsules containing Product ("Minimum Annual Sales") in the United States and Canada as set forth immediately below for the year ending on the anniversary of the applicable Launch Date in such country (subject to adjustment for introduction of generic competing products in the Territory as described below):

Minimum Annual Sales – United States

Launch Date Anniversary	Minimum Number of Capsules to Be Sold
[***]	[***]
[***]	[***]
[***]	[***]

Minimum Annual Sales – Canada

Launch Date Anniversary	Minimum Number of Capsules to Be Sold
[***]	[***]
[***]	[***]
[***]	[***]

No Minimal Annual Sales requirements shall apply after the [***] anniversary of the applicable Launch Date or in respect of any sales of the Product in outside of the United States and Canada. Should RELIANT fail to reach the applicable Minimum Annual Sales target during any applicable year, ETHYPHARM, as its sole remedy hereunder, may, upon at least sixty (60) days prior written notice to RELIANT, convert the exclusive license granted to RELIANT pursuant to Section 3.1 to a non-exclusive license solely in that country of the Territory where RELIANT failed to meet the Minimum Annual Sales target; *provided*, *however*, that RELIANT shall have the option, but not the obligation, to make an additional payment (the "Make-Whole Payment"), in addition to any other payments due to ETHYPHARM under Section 9.1 in respect of sales of the Product in such country for said year, such that ETHYPHARM receives an aggregate amount for sales of Product in such country for said year that is not less than the amount ETHYPHARM would have received under this Agreement had RELIANT achieved the applicable Minimum Annual Sales target in such country for said year, in which case ETHYPHARM shall have no right to convert the License to a non-exclusive license in such country. For the purpose of calculating the amount of the Make-Whole Payment, RELIANT shall use the [***] in such country for said year. For the avoidance of doubt, the parties agree and acknowledge that sales of the Product by RELIANT's sublicensees shall be included for the purposes of determining whether the applicable Minimum Annual Sales target has been satisfied. The parties agree that in the event that any generic products that compete with the Product are introduced in the Territory during the period while any Minimum Annual Sales targets remain in effect, the applicable Minimum Annual Sales targets shall be reduced by [***] percent ([***] %) in the [***] (pro rated for generic introductions in the middle of the applicable year), by [***] percent ([***] %) in [***] and by [***] percent ([***] %) for [***] .

3.5 Competing Dosage Forms. RELIANT may not, within [***] years of the first Launch Date in the Territory, develop, have developed, promote, distribute or market any

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Competing Dosage Form within the Territory, without the prior written consent of ETHYPHARM; *provided, however*, that the foregoing restriction shall not prevent RELIANT from developing, having developed, promoting, distributing or marketing any Competing Dosage Form within the Territory provided that RELIANT pays ETHYPHARM royalties in respect of such Competing Dosage Form in accordance with Section 9 of this Agreement; *provided, further*, that should RELIANT decide to develop or have developed any Competing Dosage Form within the Territory, RELIANT shall send ETHYPHARM a written notification of such decision in order to enable ETHYPHARM to propose within a maximum period of sixty (60) days from receipt of the written notification a similar or comparable product to the Competing Dosage Form; *provided, further*, RELIANT agrees to give ETHYPHARM at least ten (10) days prior written notice of RELIANT's decision to promote, distribute or market any existing any Competing Dosage Form within the Territory. For the avoidance of doubt, the parties agree and acknowledge that the restrictions in this Section 3.5 shall not apply to any Combination Product.

4. **COMPENSATION – LICENSE FEES AND MILESTONE PAYMENTS**

4.1 License Fees. In consideration of the services by ETHYPHARM to research and develop the Product, pursuant to the License and other rights granted hereunder, RELIANT shall pay to ETHYPHARM license fees, up to an aggregate amount of US$[***] , as follows:

(a) US$[***] upon full execution by the parties of this Agreement;

(b) US$[***] within five (5) Business Days of the acceptance for filing by the FDA of RELIANT's NDA for the marketing and sale by RELIANT of the Product in the United States, which NDA shall contain all sections thereof and other supporting documentation required to be prepared and delivered by ETHYPHARM pursuant to Section 2.5 hereof;

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(c) US$[***] if and when cumulative Net Sales (measured from the first Launch Date) exceed US$[***] , which amount shall be payable at such time as the next payment is due to ETHYPHARM in respect of Net Sales pursuant to Section 9.1 hereof.

4.2 Milestone Payments. In addition to the license fees set forth above, RELIANT shall pay to ETHYPHARM milestone payments following the delivery and acceptance of materials necessary for clinical development of the Product, the filing of the Regulatory Applications and the issuance of the Applicable Permits required for RELIANT to market and sell the Product in the Territory, up to an aggregate amount of US$[***] , as follows:

(a) US$[***] within five (5) Business Days following receipt and acceptance by RELIANT of the first delivery of validated clinical trial supplies of Product from ETHYPHARM pursuant to Section 5.1 hereof;

(b) US$[***] following receipt and acceptance by RELIANT of sufficient quantities of the Product in Finished Dosage Form batches from ETHYPHARM necessary to satisfy the requirements of the Act (including, without limitation, the NDA and other applicable permits) and to obtain regulatory approval to commence marketing of the Product in the United States, said sum being payable in three (3) installments as follows:

(i) US$[***] within five (5) Business Days of RELIANT's receipt and acceptance of the first delivery of the Product in Finished Dosage Form pursuant to Section 5.2 hereof;

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(ii) US$500,000 within five (5) Business Days of issuance to RELIANT of the NDA by the FDA for marketing the Product in the United States; and

(iii) US$500,000 within five (5) Business Days of the six (6) month anniversary of the first Launch Date in the Territory.

4.3 ETHYPHARM Failure to Abide by Product Development Program. In the event that ETHYPHARM either (a) fails to prepare, deliver and, as applicable, file with the appropriate Governmental Authorities any of the materials required to be so prepared, delivered and/or filed by or on behalf of ETHYPHARM pursuant to the Product Development Program or any provision hereof, including, without limitation, Section 2.5 hereof, by the applicable deadline, or (b) fails to deliver to RELIANT any Product required to conduct any clinical trials, file any Regulatory Applications or that is otherwise required to be delivered by ETHYPHARM under this Agreement or the Product Development Program by the applicable deadline, then the amount of the payments due to ETHYPHARM pursuant to Sections 4.1 and 4.2 hereof shall be reduced by the amount of US$3,000 for each day or portion thereof after such deadline with respect to which ETHYPHARM failed to make such delivery or file such materials. The parties agree that this provision is in addition to any other rights or remedies either of the parties may have under this Agreement. Notwithstanding the foregoing, the parties agree (a) to meet and discuss in good faith any revised deadlines under the Product Development Program, and (b) to provide each other with notice of, and a reasonable

opportunity to resolve or mitigate, any problem or other issue that arises with respect to the Product Development Program and/or the NDA.

4.4 Refund. Any payments made to ETHYPHARM pursuant to Sections 4.1 or 4.2 above which are made prior to the Approval Date for the marketing and sale of the Product by RELIANT in the United States shall be refunded in full by ETHYPHARM to RELIANT within five (5) Business Days following RELIANT's notice to ETHYPHARM of the rejection of the NDA by the FDA, or an order of *"non-approval"* or similar FDA comment, if such rejection order or comment is due to any acts or omissions of ETHYPHARM or any of its suppliers, employees, agents or Affiliates, including, but not limited, to any acts or omissions that consist of or result in one or more of the following:

(a) lack of Product stability;

(b) lack of documentation regarding Product stability;

(c) inadequacies in the DMF, the CMC or any other materials prepared or provided by or on behalf of ETHYPHARM that are included in the Regulatory Applications; and/or

(d) failure to comply with any Applicable Laws or Applicable Permits regarding the manufacture or packaging of the Product, in any formulation or dosage form, including, without limitation, failure to comply with cGMP requirements, or properly maintain any documentation required under Applicable Law.

In the event of any of the foregoing, RELIANT shall promptly notify ETHYPHARM of any such rejection of the NDA and the reason therefor, and

shall provide to ETHYPHARM copies of relevant documents in support of its request for a refund as may reasonably be requested by ETHYPHARM. The parties agree that, in the event that, following a rejection of the NDA, RELIANT continues to intend to market the Product outside of the United States they shall negotiate in good faith a reduction of the refund (*i.e.*, the amount entitled to be retained by ETHYPHARM) under this Section 4.4.

4.5 Method of Payment. All payments required to be paid under this Agreement by RELIANT to ETHYPHARM, or ETHYPHARM to RELIANT, shall be paid in United States dollars by wire transfer of immediately available funds to a dollar-denominated account located in the United States pursuant to written payment instructions, which shall be delivered to by the party entitled to such payment at least five (5) Business Days prior to the date such payment is due. Such payment shall be deemed to have been made upon the issuance of a federal reference number for the wire transfer of said funds.

5. **DELIVERY OF PRODUCT FOR CLINICAL AND REGULATORY PURPOSES; PRODUCT LAUNCH; ADDITIONAL MANUFACTURING FACILITY**

5.1 Clinical Formulations and Placebos. ETHYPHARM shall manufacture, deliver and sell to RELIANT such quantities of validated clinical formulations of the Product, in such formulations and dosage forms as requested by RELIANT, together with matching quantities of placebos, to enable RELIANT to conduct all clinical trials to be conducted pursuant to the Product Development Program established hereunder. All Product, regardless of formulation or dosage form, and placebos for use by RELIANT in clinical trials shall be: (a) sold to RELIANT at ETHYPHARM's actual cost as determined in accordance with Exhibit D attached

hereto; and (b) delivered by ETHYPHARM within thirty (30) days of ETHYPHARM's receipt of RELIANT's order therefor.

5.2 Registration Batches. ETHYPHARM shall manufacture, deliver and sell to RELIANT such quantities of full commercial scale batches of the Product, in such formulations and dosage forms as requested by RELIANT, determined by RELIANT to be necessary to satisfy requirements under Applicable Law or Applicable Permit (including, without limitation, in connection with the filing and approval of an NDA with the FDA) to market the Product in the United States. All Product, in whatever formulation, for use by RELIANT to satisfy such requirements shall be: (a) sold to RELIANT at ETHYPHARM's actual cost as determined in accordance with Exhibit D attached hereto; and (b) delivered by ETHYPHARM within thirty (30) days of ETHYPHARM's receipt of RELIANT's order therefor.

5.3 Launch and Promotion of the Product. RELIANT shall use its commercially reasonable efforts to commence commercial sales of the Product in the United States within a reasonable time and in any event not later than six (6) months after receipt of the Applicable Permits are issued. For a period of three (3) years following the first Launch Date in the United States, RELIANT shall use its commercially reasonable efforts to promote the Product utilizing a sales force consisting of at least [***] sales representatives. In the event that RELIANT does not use its commercially reasonable efforts to commence commercial sales of the Product within the six (6) month period specified herein, then ETHYPHARM, as its sole remedy hereunder, may, upon at least sixty (60) days prior written notice to RELIANT, convert the exclusive license granted to RELIANT pursuant to Section 3.1 to a non-exclusive license solely in that country of the Territory where RELIANT failed to use its

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commercially reasonable efforts to commence commercial sales of the Product within the six (6) month period specified herein; *provided, however*, that RELIANT shall have the option, but not the obligation, for a period not to exceed eighteen (18) months to make an additional payment of $3000 per day with respect to the United States ($300 per day with respect to each of Canada and Mexico), payable monthly in arrears, in which case ETHYPHARM shall not have the right to convert the License to a non-exclusive license in said country (it being agreed that such payments shall be made until such time as commercial sales of the Product commence in the country in question).

5.4 Additional Manufacturing Facility. On or prior to the first Launch Date of the Product in the Territory, ETHYPHARM shall establish, validate and certify an additional manufacturing facility for the Product, which facility may be owned by ETHYPHARM or a third party contract manufacturer (such facility, the "Additional Manufacturing Facility"). ETHYPHARM shall certify in writing to RELIANT that the Additional Manufacturing Facility (and, as applicable, any third party contract manufacturer): (i) has the requisite capacity to satisfy ETHYPHARM's production, packaging and delivery obligations, and to meet RELIANT's order requirements, hereunder with respect to the Product in accordance with the Specifications and the terms and conditions of this Agreement; (ii) complies and will comply with all Applicable Laws and holds all Applicable Permits necessary for the manufacture and packaging of the Product in compliance with cGMP; and (iii) has and will have the irrevocable right to use all Intellectual Property and Confidential Information of ETHYPHARM necessary to manufacture and package the Product in any formulation or dosage form required

hereunder, in accordance with the Specifications and the terms and conditions of this Agreement.

5.5 RELIANT Third-Party Beneficiary Rights. In the event that ETHYPHARM contracts with any third party (other than RELIANT or any of RELIANT's Affiliates) to establish the Additional Manufacturing Facility and to provide the manufacturing services required under Section 5.4 hereof (such contract, a "Contract Manufacturing Agreement"): (a) ETHYPHARM shall deliver to RELIANT a true and complete copy of such Contract Manufacturing Agreement promptly following the execution thereof; (b) such Contract Manufacturing Agreement shall explicitly provide that RELIANT is a third party beneficiary thereof with the right to enforce the provisions thereof for its benefit; and (c) such Contract Manufacturing Agreement shall contain such terms and conditions that are consistent with those contained herein (including, without limitation, the obligation to manufacture, package, sell and deliver Product to RELIANT, and the right of RELIANT to conduct an audit an inspection of the Additional Manufacturing Facility pursuant to Section 7.10 hereof). The parties agree and acknowledge that the foregoing requirements are necessary in order that RELIANT may be assured that it will continue to be supplied with the Product in accordance with the terms and conditions of this Agreement, and meet its contractual obligations to various third-parties. Notwithstanding the foregoing, RELIANT shall not be required to make any payment or render any performance hereunder to any Person other than ETHYPHARM, except as RELIANT may agree in writing.

6. **OWNERSHIP AND USE OF INTELLECTUAL PROPERTY; DEVELOPMENT OF COMBINATION PRODUCTS**

6.1 Ownership. Subject to the terms hereof, including, without limitation, the License and other rights granted by ETHYPHARM to RELIANT hereunder, all existing and future Intellectual Property of the parties with respect to the Product shall be owned as follows:

(a) other than as provided below or elsewhere in this Agreement, all Intellectual Property owned by any party hereto on the date hereof shall continue to be owned by such party;

(b) any Intellectual Property developed, created or discovered solely by ETHYPHARM and subject to the license granted hereunder during the Term of this Agreement relating to the Product and its manufacturing shall be owned by ETHYPHARM; and

(c) any Intellectual Property developed, created or discovered by or on behalf of RELIANT during the Term of this Agreement relating to any of the clinical development and methods of use of the Product, in any formulation or dosage form, and any Intellectual Property that is otherwise developed by RELIANT shall be owned by RELIANT.

Each party agrees to execute and deliver to the party that owns or is entitled to own any Intellectual Property hereunder, such instruments of transfer and assignment as may be requested by the owner party to vest fully in such party the ownership rights in said Intellectual Property; *provided, however*, that each party hereto shall be entitled, during the Term of this Agreement, to use and practice any and all Intellectual Property owned by the other party of the types

described in foregoing clauses (a), (b) and (c), without additional payment or royalty, for purposes not inconsistent with this Agreement and in accordance with the terms and conditions hereof. In any event, RELIANT may not use ETHYPHARM's Intellectual Property to apply for a patent outside the Territory. Each party shall be free to use and practice its own Intellectual Property in any application not inconsistent with the terms of this Agreement without the consent of the other and without an obligation to notify the other party of such intended use or to pay royalties or other compensation to the other by reason of such use during the Term of this Agreement and thereafter.

6.2 Patents. Each party shall be responsible, at its own expense, for filing and prosecuting such patent applications, as it deems appropriate, and for paying maintenance fees on any patents issuing therefrom, for the term of this Agreement, with respect to inventions owned by it that relate to or are used in connection with the manufacture, packaging, sale or use of the Product and which are necessary for, used in connection with or otherwise related to the performance of this Agreement by either party hereto. Notwithstanding anything herein to the contrary, ETHYPHARM, at its sole cost and expense, shall continue to prosecute and maintain each of the Patents and shall keep RELIANT advised of all actions relative to the same. If ETHYPHARM fails to carry out the obligations set forth in this Section 6.2 with respect to the Patents, RELIANT may carry out such obligations on ETHYPHARM's behalf at ETHYPHARM's cost and may set off such cost against any amounts due to ETHYPHARM hereunder thereafter. Each party shall promptly render all necessary assistance reasonably requested by the

other party in applying for and prosecuting patent applications based on Intellectual Property owned by such other party under this Agreement. Except as otherwise provided herein, patents covering joint inventions, if any, shall be owned by the parties jointly, and the parties shall share equally in the expenses of filing for and maintaining such patents and any royalties attributable thereto. ETHYPHARM's obligations in respect of patents pursuant to this Section 6.2 shall apply only to those patents used in the manufacture of the Product or otherwise related to the Product or necessary for the full and timely performance of ETHYPHARM's obligations under this Agreement.

6.3 Notice of Infringement. If either party shall learn of (a) any claim or assertion that the manufacture, use or sale of the Product under, or any use of Intellectual Property contemplated by, this Agreement, or any other action taken by either party in performance of its obligations hereunder infringes, misappropriates or otherwise violates the Intellectual Property rights of any third party, or (b) the actual or threatened infringement, misappropriation or other violation by any third party of the Intellectual Property rights of any party hereto that are the subject of this Agreement, then the party becoming so informed shall as soon as reasonably practicable, but in all events within fifteen (15) Business Days thereof, notify the other party to this Agreement of such claim or assertion, or actual or threatened infringement, misappropriation or other violation.

6.4 ETHYPHARM Indemnified Claims. In the event that any third party brings or threatens to bring a claim against either party hereto and/or any of its Affiliates that alleges or demonstrates infringement of such third party's Intellectual

Property rights arising out of, resulting from or otherwise related to (i) the Product, including the formulation, the manufacture of the Product or the micronization of the API and the non-active ingredients contained therein, or (ii) any ETHYPHARM Intellectual Property used by RELIANT, its Affiliates, sublicensees or agents as contemplated by this Agreement (such claims, together, "ETHYPHARM Indemnified Claims"), ETHYPHARM shall defend such action at its own cost and expense, and shall, at its own cost and expense, indemnify and hold harmless RELIANT and RELIANT's Affiliates, officers, managers, employees, trustees, representatives, consultants, sublicensees and agents (the "RELIANT Infringement Indemnitees") as set forth in Section 6.7 below. With respect to the manufacture (but not the micronization) of the API, in the event that (a) any third party brings or threatens to bring a claim against either party hereto and/or any of its Affiliates that alleges or demonstrates infringement of such third party's Intellectual Property rights arising out of, resulting from or otherwise related to the manufacture of the API, and (b) ETHYPHARM's supplier of the API fails to defend, indemnify and hold harmless ETHYPHARM from such claim, both parties shall cooperate in the defense of such action and equally bear the cost and expenses thereof (it being agreed, in any event, that any indemnification or other rights or amounts received by ETHYPHARM from such supplier in respect of or as result of such claim shall be applied to the defense of such claim hereunder).

6.5 RELIANT Indemnified Claims. In the event that any third party brings or threatens to bring a claim against either party hereto and/or any of its Affiliates

that alleges or demonstrates infringement of such third party's Intellectual Property rights arising out of, resulting from or otherwise related to any RELIANT Intellectual Property used by RELIANT, its Affiliates, sublicensees or agents as contemplated by this Agreement (such claims, together, "RELIANT Indemnified Claims"), RELIANT shall defend such action at its own cost and expense, and shall, at its own cost and expense, indemnify and hold harmless ETHYPHARM, its Affiliates, officers, managers, employees, representatives, consultants and agents (the "ETHYPHARM Infringement Indemnitees") as set forth in Section 6.8 below.

6.6 Infringement Indemnification by ETHYPHARM. Notwithstanding any other provisions of this Agreement, ETHYPHARM will defend, indemnify and hold harmless the RELIANT Infringement Indemnitees from and against any and all liabilities, losses, damages, actions, claims and expenses suffered or incurred by RELIANT Infringement Indemnitees (including reasonable attorneys' fees, court costs and expert witnesses' fees) resulting from any ETHYPHARM Indemnified Claims so long as any such claim does not arise from RELIANT's breach of this Agreement, or arise from RELIANT's negligent or intentionally wrongful conduct (it being expressly understood that RELIANT's reasonable exercise of its rights hereunder with respect to the use of any ETHYPHARM Intellectual Property in accordance with this Agreement and RELIANT's reasonable exercise of its rights hereunder in accordance with this Agreement shall not be deemed a RELIANT's negligent or intentional wrongful conduct as pertaining to violation of another party's Intellectual Property rights).

6.7 Infringement Indemnification by RELIANT. Notwithstanding any other provisions of this Agreement, RELIANT will defend, indemnify and hold harmless the ETHYPHARM Infringement Indemnitees from and against any and all liabilities, losses, damages, actions, claims and expenses suffered or incurred by ETHYPHARM Infringement Indemnitees (including reasonable attorneys' fees, court costs and expert witnesses' fees) resulting from any RELIANT Indemnified Claims so long as any such claim does not arise from ETHYPHARM's breach of this Agreement, or arise from ETHYPHARM's negligent or intentionally wrongful conduct (it being expressly understood that ETHYPHARM's reasonable exercise of its rights hereunder with respect to the use of any RELIANT Intellectual Property in accordance with this Agreement shall not be deemed ETHYPHARM's negligent or intentional wrongful conduct as pertaining to violation of another party's Intellectual Property rights).

6.8 Third Party Infringement. In the event either party believes that a third party is infringing or otherwise violating any party's Intellectual Property rights with respect to or related to the Product in the Territory (a "Third Party Infringement"), ETHYPHARM and RELIANT shall consult with each other and their respective counsel in order to develop a strategy for addressing the Third Party Infringement. In the event the parties agree to take legal action to stop the Third Party Infringement, they shall agree upon legal counsel to prosecute such action. Unless the parties agree upon a different formula for sharing the expenses (including attorney and expert fees) of such action and for sharing any award or settlement, the owner of such Intellectual Property shall bear the costs of such

action and shall be entitled to any award or settlement in respect thereof. In the event that one of the parties does not desire or is otherwise unwilling to participate in the action (the "Nonparticipating Party"), the other shall be free to bring the action in its own name, at its own expense and retain any award or settlement in its entirety; *provided, however*, that if such third party infringement adversely affects either party's rights or obligations hereunder, then the costs of such action shall be borne by the owner of such Intellectual Property, regardless of which party brings or prosecutes such action. If necessary, the Nonparticipating Party shall join as a party to the suit but shall be under no obligation to participate except to the extent that such participation is required as the result of being a named party to the suit. The Nonparticipating Party shall offer reasonable assistance in connection therewith at no charge to the other party except for reimbursement of reasonable out-of-pocket expenses including reasonable attorney's fees. If either party desires to retain counsel independently, the party may do so, but it shall not relieve the party of its obligations under this Section 6.9.

6.9 Termination Resulting From Infringement. In the event that Intellectual Property belonging to any party and necessary for, used in connection with or otherwise related to the performance of this Agreement by any party hereto is determined to violate or infringe upon any Intellectual Property rights of any third party, and the owner of said Intellectual Property is unable to obtain for itself and the benefit of the other party and its sublicensees, if any, at no additional cost to said other party and/or any of its sublicensees, a license to use the Intellectual Property upon

which the claims for infringement or violation is based, then said other party shall have the right to terminate this Agreement in addition to any other rights or remedies it may have hereunder or at law or in equity.

6.10 Development of Combination Products. RELIANT shall have the right, but not the obligation, to develop and commercialize one or more products in which the API is used in combination with other pharmaceutically-active substances (each, a *"Combination Product"*); *provided, however*, that RELIANT shall have no right to use any of ETHYPHARM's Intellectual Property in connection therewith unless such development is made in cooperation with ETHYPHARM. ETHYPHARM agrees that, in the event RELIANT desires to develop one or more Combination Products with ETHYPHARM, RELIANT shall have access to ETHYPHARM's Intellectual Property and applicable personnel for the purposes of developing such Combination Products and shall grant to RELIANT such additional licenses or other rights as may be necessary or desirable, if any, for RELIANT to develop and commercialize one or more Combination Products on reasonable terms to be negotiated in good faith by the parties. The parties agree that specific terms and conditions relating to the development, license, manufacture, marketing and sale of any Combination Product developed jointly by RELIANT and ETHYPHARM shall be set forth in a separate agreement to be negotiated and executed by the parties hereto.

7. **MANUFACTURING STANDARDS; REGULATORY COMPLIANCE; SALE AND SHIPMENT OF PRODUCT; RECALL PROCEDURE AND AUDIT RIGHTS**

7.1 Standard of Manufacture. Subject to Section 7.2, ETHYPHARM shall manufacture and supply, or cause to be manufactured and supplied as expressly permitted hereunder, to RELIANT the Product pursuant to orders submitted by RELIANT in accordance with Sections 7.3 and 7.4 hereof. All Product supplied to RELIANT under this Agreement shall: (a) comply with the Specifications, all

Applicable Laws and Applicable Permits; (b) be consistent with the DMF and CMC, and produced in a facility and in a manner compliant with cGMP and all other Applicable Laws; (c) not be adulterated or misbranded within the meaning of the Act; (d) be manufactured under cGMP conditions at ETHYPHARM's facility in Chateauneuf-en-Thymerais, France, or, upon at least thirty (30) days prior written notice to RELIANT, at the Additional Manufacturing Facility, which facility shall at all times during such manufacture be an FDA-approved manufacturing facility and shall manufacture, package, label, store and handle the Product in accordance with all Applicable Laws and Applicable Permits; and (e) be in such formulation and dosage form (*e.g.*, Bulk Product Form or Finished Dosage Form) as requested by RELIANT. All shipments of the Product to be delivered to RELIANT under this Agreement, regardless of the formulation or dosage form thereof, shall be sampled and analyzed by or on behalf of ETHYPHARM to confirm that it meets the Specifications. ETHYPHARM shall deliver or cause to be delivered to RELIANT with each shipment of the Product a certificate of analysis stating that the Product in the formulations and dosage forms provided meets the applicable Specifications. ETHYPHARM agrees that neither it nor any third party manufacturer of the Product shall make any changes in the formulation, manufacture, production, packaging, storage and/or shipment of the Product without the specific written prior approval of RELIANT unless expressly required by Applicable Law (including, without limitation, cGMP or the Act), in which case ETHYPHARM shall notify RELIANT in writing immediately of such change and the reason therefor. The responsibility for the final release of

the Product delivered by ETHYPHARM to RELIANT for sale or distribution in the Territory shall remain with RELIANT.

7.2 Encapsulation by RELIANT. Notwithstanding any provision herein to the contrary, RELIANT shall not have any obligation to purchase the Product in Finished Dosage Form. RELIANT shall have the option to purchase Product in Bulk Product Form so that RELIANT may encapsulate and package the Product, either directly at its own facilitates or using the services of one or more third-parties. In the event that RELIANT elects not to have ETHYPHARM encapsulate and package the Product, ETHYPHARM agrees to provide to RELIANT, at cost, such assistance as may reasonably be requested by RELIANT to facilitate the transfer of the relevant Confidential Information and Intellectual Property of ETHYPHARM to RELIANT or such third party for the purposes of RELIANT's or such third party's encapsulation and packaging of the Product, which assistance shall be provided for a limited period of time to be reasonably agreed upon between the parties. In the event that RELIANT elects to have a third party encapsulate and package the Product using ETHYPHARM Confidential Information and Intellectual Property, RELIANT agrees that it shall obtain an agreement from such third party to keep such Confidential Information and Intellectual Property confidential in accordance with the terms of this Agreement.

7.3 Purchase and Sale; Acceptance. Subject to the terms hereof, during the Term of this Agreement, ETHYPHARM shall sell and deliver to RELIANT, and RELIANT shall purchase and accept, the Product pursuant to orders submitted by

RELIANT to ETHYPHARM in accordance with provisions hereof. All deliveries of Product shall be deemed accepted by RELIANT unless RELIANT shall deliver an Exception Notice to ETHYPHARM in accordance with Section 7.6 hereof.

7.4 Delivery Forecast; Reserve Stock of Product. Commencing on the Approval Date, RELIANT shall deliver to ETHYPHARM, and update at least once per calendar quarter, a twelve (12) month rolling forecast (the "Delivery Forecast"), which shall specify RELIANT's estimated order requirements of Product, based on manufacturing batch sizes and multiples thereof, desired formulations and dosage forms (*e.g.*, Bulk Product Form or Finished Dosage Form), and required delivery dates and destinations for the Product. Notwithstanding any provision herein to the contrary, the first ninety (90) days of the Delivery Forecast shall be binding upon the parties. RELIANT's actual orders for Product shall be equal to amounts set forth in the applicable Delivery Forecast for the relevant period, plus or minus twenty percent (20%). ETHYPHARM shall maintain, or cause to be maintained, a sufficient reserve stock of Product, in such forms as specified by RELIANT, equal to twenty percent (20%) of most recent Delivery Forecast at no additional cost to RELIANT. As requested by RELIANT, part or all of the reserve stock shall be delivered within thirty (30) days after order to RELIANT's dock in New Jersey, USA.

7.5 Shipment Costs; Title and Risk of Loss. All Product to be delivered to RELIANT under this Agreement shall be shipped by ETHYPHARM to RELIANT fully insured against risk of loss, theft, seizure and destruction at ETHYPHARM's cost. Title and risk of loss with respect to the all shipments of Product shall pass from

ETHYPHARM to RELIANT upon acceptance by RELIANT at RELIANT's dock (currently located in Somerset, New Jersey, USA). In the event of delivery at another location(s) within the Territory as may be specified by RELIANT or RELIANT's sublicensee(s), the delivery prices agreed upon between the parties shall be reconsidered in order to take into account the possible increase due to such new location or insurance and transportation costs.

7.6 RELIANT Right of Review; Exception Notice. RELIANT may conduct its own analyses on each shipment of the Product, in whatever form, delivered by or on behalf of ETHYPHARM pursuant to this Agreement. RELIANT shall notify ETHYPHARM in writing within sixty (60) days after its receipt of any shipment of Product if the same does not comply with RELIANT's order, does not meet the Specifications, is adulterated or misbranded, or is otherwise reasonably determined by RELIANT not to comply with any Applicable Laws or Applicable Permits (each such notice, an "Exception Notice"). Any dispute arising between ETHYPHARM and RELIANT concerning the conformity of any shipment of Product which cannot be settled between the two parties within thirty (30) days following RELIANT's delivery of such notice, shall be submitted to an independent expert jointly agreed to by the parties in good faith. The decision of said expert shall be binding on ETHYPHARM and RELIANT. The charges, including the fees and expenses of the expert relating to any dispute described in this Section 7.6 shall be paid by ETHYPHARM if the expert declares the delivery not to be in conformity with the provisions hereof or by RELIANT if the expert declares the delivery to be in conformity.

7.7 Notice of Third Party Audit. ETHYPHARM shall give RELIANT telephonic notice (with written confirmation) of any pending or threatened audit related to the Product (including, without limitation, the manufacture, production, sale, distribution, import/export or testing of the Product, in whatever form) by any Governmental Authority or other authorized Person, regardless of whether such audit is of ETHYPHARM or any Person (other than RELIANT) with which ETHYPHARM has an agreement related to the Product or any ingredient thereof or process used in connection with the manufacture thereof, including, without limitation, any suppliers of raw materials used in the manufacture of the Product or any third party engaged by ETHYPHARM to manufacture the Product, in each case which audit affects or could reasonably be expected to affect the performance of ETHYPHARM's obligations under this Agreement or otherwise affect RELIANT's sale or distribution of the Product (each, an "Audit"); *provided*, *however*, that ETHYPHARM shall not be required to give such notice to RELIANT of an Audit by any Person that is conducted in the ordinary course pursuant to an agreement between ETHYPHARM and such Person and not in response to any suspected violation or non-compliance. ETHYPHARM shall provide any notice to RELIANT required under this Section 7.7 as soon as practicable, but in any event within five (5) Business Days, following the date ETHYPHARM first becomes aware of such Audit, and shall provide RELIANT with any documentation or other information provided or available to it relating to any such Audit, and shall provide RELIANT reasonable opportunity to review and comment, prior to submission, any response to such Audit. ETHYPHARM

shall keep RELIANT fully apprised of the progress and results of any Audit and shall immediately provide RELIANT with the results of such Audit following its conclusion.

7.8 Notice of Regulatory Action. ETHYPHARM shall provide RELIANT with notification of its receipt (or the receipt by any Person with which ETHYPHARM has an agreement related to the Product, including, without limitation, suppliers of raw materials and contract manufacturers) of any warning, enforcement, penalty, default, non-compliance, notices of violation or any similar letters, notices, investigations, requests for information or orders from or of any Governmental Authority or other authorized Person that relate to the Product, including, without limitation, any list of observations (Form FD 483), Warning Letter, Information Letter, Establishment Inspection Report, Notice of Violation, Regulatory Letter or the like issued by the FDA. ETHYPHARM shall provide any notice to RELIANT required under this Section 7.8 as soon as practicable, but in any event within twenty-four (24) hours, following the date ETHYPHARM first receives or becomes aware of any such regulatory action, and shall provide RELIANT with any documentation or other information provided or available to it relating thereto. Notwithstanding anything herein to the contrary, ETHYPHARM maintains sole responsibility for any matter pertaining to such regulatory actions. Reliant shall have the right to review and comment on any responses of ETHYPHARM to any such regulatory action.

7.9 Recall or Withdrawal. ETHYPHARM and RELIANT will each maintain or cause to be maintained such traceability records as are necessary to permit a recall,

withdrawal or field correction of the Product (each, a "Recall"). Each party will give telephonic notice (to be confirmed in writing) to the other within twenty-four (24) hours of the receipt of any information which indicates a Recall may be necessary. The decision to conduct and the right to control a Recall will be solely that of the then current NDA owner, after appropriate consultation with the other party. Each party will cooperate fully with the other in connection with any Recall efforts. If any Recall is due to any act or omission of ETHYPHARM, ETHYPHARM will bear the cost of the Recall and replace recalled Product with conforming Product at no additional charge hereunder and will reimburse RELIANT for all of RELIANT's reasonable direct costs and expenses actually incurred by RELIANT in connection with the Recall including, but not limited to, direct costs of retrieving Product already delivered to customers and direct costs and expenses RELIANT is required to pay for notification, shipping and handling charges; *provided, however*, that for each such Recall (a) RELIANT will in good faith consult with ETHYPHARM and, to the extent commercially reasonable, implement ETHYPHARM's recommendations on how best to conduct the Recall including, without limitation, the notification and retrieval of Product, and (b) prior to any reimbursement hereunder, RELIANT will provide ETHYPHARM with detailed supporting documentation of all costs and expenses for which reimbursement is being sought. If a Recall of Product distributed is due to any act or omission of RELIANT, RELIANT will remain responsible for the costs of such Recall and will reimburse ETHYPHARM for all of the reasonable direct costs and expenses described above actually incurred by ETHYPHARM (if any)

in connection with such Recall including, but not limited to, administration of the recall and such other reasonable direct costs as may be reasonably related to the Recall. RELIANT shall not release any Product in the Territory that has not been duly controlled by RELIANT.

7.10 RELIANT Audit Right Regarding Manufacturing Facilities. Upon prior notice to ETHYPHARM and upon a minimum of one (1) month prior notice of the anticipated audit date, ETHYPHARM will permit (and will cause any owner and operator of any Additional Manufacturing Facility to permit) RELIANT to conduct an inspection and audit, of ETHYPHARM's or such third party's manufacturing facilities and operations used in the manufacturing, receiving, sampling, analyzing, storing, handling, packaging and shipping of Product, including, but not limited to, the receipt, storage and issuance of raw materials, labeling and packaging components and ingredients thereof (including, without limitation, all documentation related thereto) for the purpose of quality control and to assure compliance with cGMP, Applicable Laws, Applicable Permits and the terms of this Agreement. RELIANT may not conduct an audit hereunder more frequently than once during any six (6) month period prior to the Approval Date, or more frequently than once during any twelve (12) month period following the Approval Date; *provided*, *however*, that RELIANT may conduct an additional audit(s) in the event there is a quality or compliance issue concerning the Product or its manufacture that RELIANT deems in good faith to be material hereunder. RELIANT may conduct such audit using its own personnel or a third party auditor/inspector and shall conduct such audit, or cause such audit to be

conducted, during regular business hours and in such a manner so as to minimize interference with ETHYPHARM's or any third party's operations. ETHYPHARM will provide, and shall cause any applicable third party to provide, RELIANT with access to relevant personnel during the audit and ETHYPHARM will provide a written response to any written audit observations provided by RELIANT within thirty (30) days of ETHYPHARM's receipt thereof.

7.11 Records and Accounting by ETHYPHARM. ETHYPHARM will, with respect to each lot of Product produced and manufactured by or on behalf of ETHYPHARM hereunder, for the longer of (a) any period required under Applicable Law or Applicable Permit, and (ii) a period of two (2) years after expiry of the expiration dating of such lot, maintain accurate records of the manufacture and testing of such lot of the Product, including, without limitation, all such records which are required by Applicable Law or pursuant hereto. Access to such records will be made available by ETHYPHARM to RELIANT during normal business hours upon RELIANT's reasonable written request.

8. **PRICES**

8.1 Prices and Price Change.

(a) ETHYPHARM shall sell, and RELIANT shall buy, the Product at the following prices (subject to adjustment as provided herein):

(i) US$[***] per kg of Product delivered in Bulk Product Form; and

(ii) US$[***] per kg of Product delivered in Finished Dosage Form, plus [***] to encapsulate and package the Product into Finished Dosage Form.

At any time following the [***] anniversary of the Launch Date in the United States, the prices for the Product under this Section 8.1(a) shall be subject to adjustment in accordance with the annual increases to the index described on Exhibit C attached hereto. ETHYPHARM shall provide

[***]:Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

RELIANT at least ninety (90) days prior written notice of any proposed price increase with such supporting documentation therefor as RELIANT may reasonably request. For clinical testing, regulatory approval and compliance, and promotional sampling purposes, ETHYPHARM shall sell to RELIANT, and RELIANT shall buy from ETHYPHARM, the Product, in whatever formulation or dosage form, at such price which is the [***] (A) the prices set forth in Sections 8.1(a)(i) and (ii) above, and (B) [***] pursuant to Exhibit D. RELIANT shall indicate on any order that portion of the Product that is being purchased for clinical testing, regulatory approval and compliance, or promotional sampling purposes. On a quarterly basis, RELIANT shall file a report with ETHYPHARM reconciling its use of the Product for clinical testing, regulatory approval and compliance, and promotional sampling purposes with Net Sales and accompany that report with a payment of any balance due to ETHYPHARM. The samples of Product shall not be subject to the Net Royalty payment set forth in Section 9.1.

8.2 Payment Terms. ETHYPHARM shall send to RELIANT an invoice showing the amount due under Section 8.1 with each shipment. RELIANT shall pay ETHYPHARM the amount due within forty-five (45) days of the date of its receipt of the applicable invoice, except to the extent of a bona fide dispute between the parties with respect thereto.

9. **ROYALTIES**

9.1 Royalties.

(a) Commencing on the first Launch Date, RELIANT shall pay ETHYPHARM a Net Royalty in an amount equal to [***] percent ([***]%) of Net Sales in accordance with the provisions of this Agreement.

(b) No later than sixty (60) days after the end of each calendar quarter, RELIANT shall report to ETHYPHARM the Net Sales of the Product sold by

[***]:Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

RELIANT in the Territory and the Net Royalties due to ETHYPHARM for such period. The payment by RELIANT to ETHYPHARM shall be made within sixty (60) days after the end of each calendar quarter. RELIANT shall keep and shall require its sublicensees to keep true and accurate books of account and shall keep and maintain such records and documents as are reasonably necessary for ETHYPHARM to determine the Net Royalties due under this Agreement.

9.2 Tax Withholding. All Taxes, if any, levied under any laws or regulations applicable to the transactions contemplated by this Agreement with respect to payments due to ETHYPHARM hereunder shall be for the account of ETHYPHARM, and if required to be withheld from payments to ETHYPHARM, shall be deducted by RELIANT from such payments to ETHYPHARM. Receipts, if available, for all such withholdings shall be provided to ETHYPHARM. ETHYPHARM shall be responsible for establishing its right to claim any exemption to such charges or to its withholding, shall keep RELIANT advised in writing or the basis and status of all such exemption claims. ETHYPHARM shall be liable for, and shall indemnify RELIANT for, any penalty, interest or other assessment against RELIANT for failure to pay or withhold such charges in reliance on any such exemption claim or other advice or instructions of ETHYPHARM.

10. REPRESENTATIONS AND WARRANTIES OF THE PARTIES

10.1 Mutual Representations and Warranties of ETHYPHARM and RELIANT. Each of ETHYPHARM and RELIANT hereby represents and warrants to the other party as follows:

(a) Organization. Such party is duly organized, validly existing and in good standing under the laws of the jurisdiction of incorporation or organization. Such party has the requisite legal and company power and authority to conduct its business as presently being conducted and as proposed to be conducted by it and is duly qualified to do business in those jurisdictions where its ownership of property or the conduct of its business requires.

(b) Authority. Such party has all requisite legal and company power and authority to enter into this Agreement and to perform the services contemplated hereunder (including, in the case of ETHYPHARM, the manufacture and packaging of the Product, and the grant of the License hereunder). All company actions on the part of such party, the boards of director or managers, *conseils d'administration* or similar governing body of such party and the equity holders of such party necessary for (i) the authorization, execution, delivery and performance by such party of this Agreement, and (ii) the consummation of the transactions contemplated hereby, have been duly taken.

(c) Binding Obligation. This Agreement is a legally valid and binding obligation of such party, enforceable against such party in accordance with its terms (except in all cases as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium, or similar laws affecting the enforcement of creditors' rights generally and except that the availability of the equitable remedy of specific performance or injunctive relief is subject to the discretion of the court before which any proceeding may be brought).

(d) No Conflicts. None of the execution and delivery of this Agreement, the consummation of the transactions provided for herein or contemplated hereby, or the fulfillment by such party of the terms hereof or thereof, will (with or without notice or passage of time or both) (i) conflict with or result in a breach of any provision of the certificate or articles of incorporation or formation, by-laws, statutes, operating agreement or other governing documents of such party, (ii) result in a default, constitute a default under, give rise to any right of termination, cancellation or acceleration, or require any consent or approval (other than approvals that have heretofore been obtained) of any Governmental Authority or under any of the terms, conditions or provisions of any material note, bond, mortgage, indenture, loan, arrangement, license, agreement, lease or other instrument or obligation to which such party is a party or by which its assets may be bound, or (iii) violate any law or regulation applicable to such party or any of its assets.

(e) Insurance. Such party has in full force and effect casualty and liability insurance policies issued by issuers of internally-recognized responsibility and of such types and in such coverage amounts as customary for such party's business and consistent with industry standards.

(f) Legal Proceedings. There is no action, suit, proceeding or investigation pending or, to such party's knowledge, currently threatened, against such party or any other Person that questions the validity of this Agreement or the right of such party to enter into this Agreement, or to consummate the transactions contemplated hereby, nor does such party have knowledge that there is any basis

for the foregoing. Such party is not a party or subject to the provisions of any order, writ, injunction, judgment or decree of any Governmental Authority, which would adversely affect its rights or obligations hereunder or the transactions contemplated hereby.

(g) Consents and Approvals. All material consents, approvals, qualifications, orders or authorizations of, filings with, or notices to any Governmental Authority or any other Person required in connection with such party's execution, delivery or performance of (i) this Agreement, and (ii) the consummation of any other transaction contemplated on the part of such party hereby have been obtained, made or given.

(h) No Violation of Law; Permits. Such party is not in violation of any law or regulation (nor is such party aware of any violation of any law or regulation by any other Person), which violation could reasonably be expected to adversely affect such party's performance of its obligations hereunder or the ability of the other party to realize the intended benefits to such other party under this Agreement, and, except as otherwise contemplated hereby, such party holds each of the licenses, permits, approvals or authorizations necessary with respect to its current business and operations (and its rights and obligations contemplated hereby) in compliance with all laws and regulations.

(i) No Broker. Such party has not retained any finder, broker, agent, financial advisor or other intermediary in connection with the transactions contemplated by this Agreement.

10.2 Additional Representations, Warranties and Covenants of ETHYPHARM. ETHYPHARM hereby further represents, warrants and covenants to RELIANT, as of the date hereof and during the Term of this Agreement, as follows:

(a) Product Compliance; Title. All Product to be manufactured and delivered to RELIANT pursuant to this Agreement, in whatever formulation, dosage form or packaging, will: (i) conform to the applicable Specifications; (ii) comply with all Applicable Laws and Applicable Permits (and shall not be adulterated or misbranded within the meaning of the Act); (iii) be manufactured under cGMP conditions in an FDA-approved manufacturing facility in accordance with all Applicable Laws and Applicable Permits, and (v) upon delivery to RELIANT, good title to such Product will convey to RELIANT and such conveyance will be free and clear of any security interest, other lien or encumbrance.

(b) Permits. ETHYPHARM has and will maintain during the Term of this Agreement all Applicable Permits and such other permits, licenses and other authorizations required under Applicable Laws to permit ETHYPHARM to continue to manufacture and package the Product, including, without limitation, the Product in Bulk Product Form and Finished Dosage Form.

(c) No Investigation. There is no pending, and ETHYPHARM has no knowledge of any threatened, claim, investigation, proceeding, suit or other legal, regulatory or similar action asserting that the use, manufacture, packaging, distribution or sale of the Product constitutes an infringement of any Intellectual

Property rights of any Person, including, without limitation, any extant patents, trade secrets, trademarks or other rights of any Person.

(d) Intellectual Property. ETHYPHARM (i) is the sole owner of, and has all rights necessary to use and license to RELIANT, each of the Patents identified on the Schedule 1.42 and such Patents are the only patents required for ETHYPHARM to perform its obligations hereunder; (ii) is the sole owner of, and has all rights necessary to use and license to RELIANT, all Intellectual Property (other than the Patents) required for ETHYPHARM to perform its obligations hereunder; (iii) has not granted or transferred to, or allowed the use by, any Person in the Territory of any Intellectual Property owned or licensed by ETHYPHARM which is used in or relates to the manufacture or packaging of the Product;

(e) Product Related Intellectual Property. (i) ETHYPHARM owns or possesses adequate licenses or other Intellectual Property and Confidential Information used or held for use in connection with the Product that are necessary to permit ETHYPHARM to discharge its obligations under this Agreement with respect to the Products, including, without limitation, granting the rights and licenses granted to RELIANT under this Agreement, free and clear of any liens, licenses, obligations, transfer agreements, transfer restrictions, enforceable claims, royalties or encumbrances that would prevent ETHYPHARM from discharging its obligations under this Agreement with respect to the Product, and (ii) ETHYPHARM is unaware of any assertion or claim challenging the ownership, use or validity of any of the foregoing. Any licenses associated with the

ETHYPHARM Intellectual Property related to the Product are valid and binding and are enforceable in accordance with their respective terms, and there are no material breaches or defaults thereunder. To the extent that any of the Patents are not owned by ETHYPHARM, such Patents are owned by an Affiliate of ETHYPHARM, and ETHYPHARM licenses or has the right to use such from such Affiliate of ETHYPHARM. ETHYPHARM will not take any action to terminate, and ETHYPHARM will prevent its Affiliates from taking any action to terminate, any license or grants of rights from an Affiliate of ETHYPHARM to ETHYPHARM with respect to the Patents. ETHYPHARM has the right to grant to RELIANT all of the rights and licenses granted to RELIANT under this Agreement.

(f) No Infringement. The manufacture, use or sale of the Product by ETHYPHARM or the use of the ETHYPHARM Intellectual Property by RELIANT to develop, promote, market and sell the Product in the Territory do not, and to ETHYPHARM's knowledge will not, infringe any valid rights of any third party including *inter alia* Intellectual Property rights. The manufacture, use or sale of any raw materials supplied to or otherwise used by ETHYPHARM with respect to the Product do not, and to ETHYPHARM's knowledge will not, infringe any valid rights of any third party including *inter alia* Intellectual Property rights. To ETHYPHARM's knowledge, ETHYPHARM is unaware of any third party infringement of the Intellectual Property rights relating to the Product.

(g) Adverse Drug Experiences. ETHYPHARM has informed RELIANT of all relevant adverse drug experiences related to the Product of which it has knowledge.

(h) Expertise. ETHYPHARM has, and will at all times during the term of this Agreement have, the requisite expertise, experience and skill to perform its obligations hereunder.

(i) Labor Matters. There is no strike or other labor dispute involving ETHYPHARM or any of its employees pending, or to the knowledge of ETHYPHARM, threatened. With respect to the foregoing, individual and unrelated personnel claims or actions do not constitute a labor dispute.

(j) No Debarment. Neither ETHYPHARM nor any Person employed or engaged by ETHYPHARM in connection with any work to be performed under this Agreement has been debarred under Section 306(a) or (b) of the Act, and no debarred Person will in the future be employed or engaged by ETHYPHARM in connection with any work to be performed hereunder.

(k) Suppliers and Subcontractors. Any and all suppliers of any goods or services used in connection with the supply, manufacture, packaging, transport or handling of the Product, in whatever form and including any component or ingredient thereof, are and shall at all times during the Term hereof be in compliance with all laws, rules, regulations, orders and similar requirements, including, without limitation, all Applicable Laws, and possess all Applicable Permits, in each case required to manufacture, package, transport, handle or otherwise deal with of the Product or any component or ingredient thereof.

11. **TERM**

11.1 Basic Term. Unless sooner terminated pursuant to Section 11.2 hereof, this Agreement shall be effective from the date first above written and shall continue for an initial period of fifteen (15) years after the Launch Date of the Product in the United States (the "Initial Term"). Thereafter, the term of this Agreement shall automatically renew for consecutive periods of two (2) years each. Notwithstanding the foregoing, this Agreement may be terminated by either party at the end of the Initial Term by delivery by such party to the other written notice at least one (1) year prior to the end of the Initial Term or at the end of any renewal term by delivery for such party to the other written notice at least one hundred eighty (180) days prior to expiration of any renewal term. As used herein, "Term" refers to the Initial Term of this Agreement and any renewal terms.

11.2 Sale of Product Following Termination. Upon termination of this Agreement, ETHYPHARM shall supply, manufacture, sell and deliver to RELIANT and RELIANT shall purchase from ETHYPHARM those firm orders for Product in existence as of the date of such termination. RELIANT and its sublicensees shall have the right to dispose of existing inventory of Product, in whatever form, manufactured and delivered by ETHYPHARM and purchased by RELIANT or its sublicensees prior to the termination (over a maximum period of twelve (12) months). Notwithstanding any termination of this Agreement, all licenses and rights granted to RELIANT hereunder shall continue in full force and effect to allow RELIANT or its sublicensee(s) to dispose of any remaining Product on the termination date, and RELIANT shall be obligated to make royalty payments to ETHYPHARM as provided hereunder.

12. **EVENTS OF DEFAULT, REMEDIES AND EFFECTS OF DEFAULT**

12.1 Events of Default. An event of default under this Agreement shall be deemed to exist upon the occurrence of any one or more of the following events (each, an "Event of Default":

(a) failure by either party hereto to perform any covenant contained in this Agreement;

(b) a breach by either party of any material representation or warranty of such party under this Agreement;

(c) the entry by a court of competent jurisdiction of a decree or order of relief with respect to any party in any voluntary or involuntary case or proceeding under any bankruptcy, insolvency or similar law, or the appointment of a receiver, liquidator, assignee, trustee or similar official of that party, which decree or order is consented to by the party or continues unstayed and in effect for a period of sixty (60) days;

(d) the filing by any party of a voluntary petition or acquiescence in or failure to contest an involuntary petition or an involuntary petition filed against such party that is not dismissed within sixty (60) days, in any case or proceeding under any bankruptcy, insolvency or similar law, or the making by any party of an assignment for the benefit of its creditors; or

(e) the involuntarily dissolution or liquidation of any party; *provided*, with respect to any Event of Default under clause (a) or (b) above, such default continues (i) for a period of ninety (90) days after delivery by the non-defaulting party of written notice of such default, or (ii) if the defaulting party shall commence good faith remediation of such default within such ninety (90)

day period and shall thereafter proceed with all due diligence to cure such default, and such default is not cured within such longer period (not to exceed ninety (90) days) as shall be reasonably necessary for such party to cure the same with all due diligence.

12.2 Remedies for Breach; Termination. Upon the occurrence and during the continuation of any Event of Default hereunder, the party not in default may terminate this Agreement and pursue any other remedies provided under this Agreement or available at law or equity.

12.3 Technology Transfer. In the event of any termination of this Agreement as a result of any Event of Default caused by or related to any act or omission by or on behalf of ETHYPHARM or any of its Affiliates or agents, ETHYPHARM undertakes as a continuing obligation, notwithstanding such termination, that it will use all reasonable endeavors to effect a transfer of the Intellectual Property and Confidential Information used by ETHYPHARM in the performance of its obligations hereunder to RELIANT or to a third-party manufacturer designated by RELIANT, and/or grant such licenses as may be necessary to enable RELIANT or such third-party manufacturer to manufacture and package the Product in such form and quantities contemplated hereby for the Territory, subject at all times to ETHYPHARM receiving reasonable undertakings as to confidentiality in respect of any ETHYPHARM Intellectual Property that is so transferred or licensed.

12.4 Right of First Offer In Connection with Divestiture. In the event RELIANT decides to divest the Product in the Territory, for whatever reason, ETHYPHARM will be granted a right of first offer to acquire all rights in relation

with the Product and the relevant Intellectual Property and Confidential Information belonging to RELIANT pursuant to terms no less favorable to ETHYPHARM than those proposed to be offered third-parties, such right to be exercised within a maximum period of sixty (60) days from date of official written notification by RELIANT to ETHYPHARM. In the event ETHYPHARM does not exercise its right, RELIANT undertakes to transfer to its assignee all rights and obligations vis-à-vis ETHYPHARM provided for in this Agreement.

13. **INDEMNIFICATION AND INSURANCE**

13.1 Indemnification of RELIANT. ETHYPHARM shall indemnify and hold harmless RELIANT and its Affiliates and their respective equityholders, managers, directors, officers, trustees, agents and employees (collectively, "RELIANT Indemnified Parties") from and against all damages, losses, expenses, claims, demands, suits, penalties, judgments or administrative and judicial orders and liabilities (including reasonable legal fees and expenses) incurred, assessed or sustained by any RELIANT Indemnified Party with respect to or involving or arising out of (i) a breach by ETHYPHARM of any representation, warranty, duty or covenant of ETHYPHARM hereunder, or (ii) any negligent act or omission, or willful misconduct of ETHYPHARM or any of its Affiliates or agents.

13.2 Indemnification of ETHYPHARM. RELIANT shall indemnify and hold harmless ETHYPHARM and its Affiliates and their respective equityholders, managers, directors, officers, trustees, agents and employees (collectively, "ETHYPHARM Indemnified Parties") from and against all damages, losses, expenses, claims, demands, suits, penalties, judgments or administrative and judicial orders and liabilities (including reasonable legal fees and expenses) incurred, assessed or

sustained by any ETHYPHARM Indemnified Party with respect to or involving or arising out of (i) a breach by RELIANT of any representation, warranty, duty or covenant of RELIANT hereunder, or (ii) any negligent act or omission, or willful misconduct of RELIANT or any of its Affiliates or agents.

13.3 Notice and Legal Defense. Promptly after receipt by a party hereunder of any claim or notice of the commencement of any action, administrative or legal proceeding, or investigation as to which the indemnity provided for in Section 13.1 and 13.2 hereof may apply, the party seeking indemnification shall notify the indemnifying party of such fact. The indemnifying party shall assume the defense thereof; *provided, however*, that if the defendants in any such action include both the party seeking indemnification and the indemnifying party and the party seeking indemnification shall reasonably conclude that there may be legal defenses available to it which are different from or additional to, or inconsistent with, those available to the indemnifying party, the party seeking indemnification shall have the right to select separate counsel (reasonably acceptable to the indemnifying party) to participate in the defense of such action on behalf of such party seeking indemnification, at the indemnifying party's expense.

13.4 Insurance. Each party shall, at its own cost, cause the other party and its respective agents, employees, officers, shareholders and contractors to be added as additional insureds on all policies of general commercial liability insurance and product liability insurance covering such party, which coverage shall have limits of liability which are commercially reasonable but shall not be less than US$10,000,000 per loss occurrence. Each policy shall contain an endorsement

which provides that any amendments or cancellation of any such policy shall not be effective unless the other party shall have been given thirty (30) days prior written notice of any such intended amendment or cancellations. Within five (5) days of the beginning of each policy period, each party shall deliver to the other a certificate evidencing the coverage required hereby and the amount thereof. Such coverage shall be maintained for not less than five (5) years following termination of this Agreement or if such coverage is of the *"claims made"* type, for ten (10) years following termination of this Agreement.

14. **MISCELLANEOUS**

14.1 Assignment.

(a) Subject to subsection 14.1(b), below, this Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and assigns permitted under this Agreement.

(b) Neither party may assign this Agreement or any of its rights hereunder or delegate its performance of its obligations hereunder without the express prior written consent of the other party, except that either party may assign or delegate any of its rights or obligations under this Agreement to an Affiliate or subsidiary of the assigning party; provided that the assigning party shall, by express written agreement, (i) remain liable for any obligations and liabilities incurred by it under this Agreement, and (ii) be made liable for all obligations and liabilities of the assignee following such assignment; provided further, that the assignee shall expressly acknowledge, by written agreement, its assumption of all obligations and liabilities under the Agreement. Any attempted assignment in violation of this provision shall be deemed a material breach of this

Agreement. For purposes of this Section 14.1, a transfer to an unaffiliated third party, by either RELIANT or ETHYPHARM, of all or substantially all of its assets or a controlling interest in its stock or other equity interests, shall be deemed an assignment; provided that, any of the following shall not be deemed an assignment and shall be permitted without consent from ETHYPHARM or RELIANT, as applicable, thereto: (1) any conversion of RELIANT from a limited liability company to a corporation; (2) any issuance by RELIANT or ETHYPHARM of securities in connection with any financing transaction or public offering, (3) any acquisition or merger involving RELIANT or ETHYPHARM if the acquiring or surviving company is a reputable company engaged in the pharmaceutical business with a history of substantial regulatory compliance, and/or (4) any merger or acquisition to which the other party hereto has given its prior written consent. Nothing herein shall preclude RELIANT from sublicensing any or all of its rights hereunder in accordance with the terms of this Agreement, or from entering into agreements with third-parties to co-promote or assist RELIANT in the sale, marketing or promotion of the product provided that the foregoing shall not relieve RELIANT of any of its obligations hereunder.

14.2 Confidentiality. Each party will hold Confidential Information of the other party and its Affiliates in complete confidence and will not, without the prior written consent of the other, use or disclose it in whole or in part to any Person other than for the purposes set forth in this Agreement for a period ending five (5) years following expiration of this Agreement. Each party will be entitled to disclose any such Confidential Information to such of its professional advisers, directors,

managers, officers and employees who are directly concerned with this Agreement and its implementation and whose knowledge of such information in the opinion of the disclosing party is necessary for these purposes. Each party will use its reasonable efforts to ensure that each individual to whom such a disclosure is made adheres to the terms of this undertaking as if he or she were a party hereto. Each party may disclose such Confidential Information to the extent such disclosure is required by law; *provided, however*, that the disclosing party shall (to the extent permitted) give the other party prior notice of such required disclosure and cooperate with such other party in order that such other party may seek a protective order or relief to prevent or limit the Confidential Information required to be disclosed; *provided, further*, that the disclosing party shall only disclose that portion of the Confidential Information that such party is advised by its legal counsel is required to be disclosed by law and shall seek assurances that such Confidential Information will be maintained in confidentiality by the receiving party.

14.3 Exchange of Information. RELIANT will periodically inform ETHYPHARM with information regarding unit sales by market region in the Territory. Each party will timely report to the other any information concerning any serious adverse event (as defined by the Act) associated with clinical uses, studies, investigations or tests of the Product, whether in Bulk Product Form or in Finished Dosage Form. In reporting such incidents, the reporting party will use reasonable efforts to indicate whether, in its judgment, any of them are unexpected or unusual in type, incidence or severity.

14.4 Force Majeure. If either party is prevented from complying, either totally or in part, with any of the terms or provisions set forth herein by reason of *force majeure*, including, by way of example and not of limitation, fire, flood, explosion, storm, strike, lockout or other labor dispute, riot, war, rebellion, accidents, acts of God, acts of Governmental Authorities, failure of suppliers or any other similar cause, in each case to the extent beyond its reasonable control, said party will provide written notice of same to the other party. Said notice will be provided within five (5) Business Days of the occurrence of such event and will identify the requirements of this Agreement or such of its obligations as may be affected, and to the extent so affected, said obligations will be suspended during the period of such disability. If any raw materials, facility systems or capacity is used for both the manufacture and packaging of the Product in satisfaction of ETHYPHARM's obligations hereunder and any other product or purposes, any necessary allocation will be made as between ETHYPHARM's needs, RELIANT's needs and the needs of any other party with whom ETHYPHARM has firm contractual obligations on a basis no less favorable than pro rata on a volume basis. The party prevented from performing hereunder will use its commercially reasonable efforts to remove such disability and will continue performance whenever such causes are removed. The party so affected will give to the other party a good faith estimate of the continuing effect of the *force majeure* condition and the duration of the affected party's nonperformance. If the period of any previous actual nonperformance of ETHYPHARM because of ETHYPHARM *force majeure* conditions plus the anticipated future period of

ETHYPHARM nonperformance because of such conditions will exceed an aggregate of ninety (90) days within any six (6) month period, RELIANT may terminate this Agreement immediately by written notice to ETHYPHARM. If the period of any previous actual nonperformance of RELIANT because of RELIANT *force majeure* conditions plus the anticipated future period of RELIANT nonperformance because of such conditions will exceed an aggregate of ninety (90) days within any six (6) month period, ETHYPHARM may terminate this Agreement immediately by written notice to RELIANT. When such circumstances as those contemplated herein arise, the parties will discuss in good faith, what, if any, modification of the terms set forth herein may be required in order to arrive at an equitable solution.

14.5 Amendment. No amendment or modification of the terms of this Agreement shall be binding on either party unless in writing and signed by both parties.

14.6 No Implied Waiver. Failure by either party hereto on one or more occasions to avail itself of a right conferred by this Agreement shall in no event be construed as a waiver of such party's right to enforce said right in the future.

14.7 Choice of Law. This Agreement and all rights and obligations hereunder, including matters of construction, validity and performance, shall be governed by and construed in accordance with the laws of the state of New Jersey, without giving effect to the conflict of laws principles thereof.

14.8 CONSENT TO JURISDICTION; AGENT FOR SERVICE OF PROCESS. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY AGREES THAT ANY SUIT, ACTION, PROCEEDING OR CLAIM AGAINST SUCH

PARTY ARISING OUT OF OR IN ANY WAY RELATING TO THIS AGREEMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED HEREBY, OR ANY JUDGMENT ENTERED BY ANY COURT IN RESPECT THEREOF, MAY BE BROUGHT OR ENFORCED IN THE STATE OR FEDERAL COURTS LOCATED IN THE COUNTY OF SOMERSET IN THE STATE OF NEW JERSEY AND THE COMPANY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ANY OBJECTION WHICH IT MAY NOW OR HEREAFTER HAVE TO THE VENUE OF ANY PROCEEDING BROUGHT IN THE COUNTY OF SOMERSET IN THE STATE OF NEW JERSEY AND FURTHER IRREVOCABLY WAIVES ANY CLAIMS THAT ANY SUCH PROCEEDING HAS BEEN BROUGHT IN AN INCONVENIENT FORUM. ETHYPHARM HEREBY IRREVOCABLY AND UNCONDITIONALLY APPOINTS ETHYPHARM CORP., 22 UNION AVENUE, BALA-CYNWYD, PENNSYLVANIA 19004, USA (ATTENTION: HAFID TOUAM, VICE PRESIDENT), AS AGENT FOR SERVICE OF PROCESS UNDER THIS AGREEMENT.

14.9 WAIVER OF JURY TRIAL. THE PARTIES HERETO HEREBY EXPRESSLY WAIVE ANY RIGHT TO A TRIAL BY JURY IN ANY ACTION OR PROCEEDING TO ENFORCE OR DEFEND ANY RIGHT, POWER, OR REMEDY UNDER OR IN CONNECTION WITH THIS AGREEMENT OR ANY OF THE RELATED AGREEMENTS OR UNDER OR IN CONNECTION WITH ANY AMENDMENT, INSTRUMENT, DOCUMENT, OR

AGREEMENT DELIVERED OR WHICH MAY IN THE FUTURE BE DELIVERED IN CONNECTION HEREWITH OR THEREWITH OR ARISING FROM ANY RELATIONSHIP EXISTING IN CONNECTION WITH THIS AGREEMENT OR ANY RELATED AGREEMENT, AND AGREE THAT ANY SUCH ACTION SHALL BE TRIED BEFORE A COURT AND NOT BEFORE A JURY. THE TERMS AND PROVISIONS OF THIS SECTION CONSTITUTE A MATERIAL INDUCEMENT FOR THE PARTIES ENTERING INTO THIS AGREEMENT.

14.10 Notice . Any notice and other communication required or permitted to be given hereunder shall be in writing and shall be deemed given when delivered personally, telecopied or received by registered mail, return receipt requested, or from an internationally-recognized courier service to the parties at the following addresses:

if to ETHYPHARM, to:

ETHYPHARM S.A. and ETHYPHARM INDUSTRIES, S.A.
194, Bureaux de la Colline – Bâtiment D
92213 Saint Cloud
France
Attn: Gérard M. Leduc, Managing Director
Fax: +33 1 41 12 29 89

with a copy sent simultaneously to:

ETHYPHARM CORP.
22 Union Avenue
Bala-Cynwyd, Pennsylvania 19004
USA
Attn: Hafid Touam, Vice President
Fax: +1 (601) 667-5342

if to RELIANT, to:

RELIANT PHARMACEUTICALS, LLC
110 Allen Road
Liberty Corner, New Jersey 07938
USA
Attn.: Joseph Krivulka, President and
Michael Lerner, General Counsel
Fax:

with a copy sent simultaneously to:

Latham & Watkins
Sears Tower, Suite 5800
Chicago, Illinois 60606
USA
Attn: Michael A. Pucker
Fax:

14.11 English Language. This Agreement and all exhibits, schedules, reports, notices and all other communications and proceedings with respect hereto shall be written and/or conducted solely in the English language.

14.12 Execution of Additional Documents. Each party hereto agrees to execute such further documents or agreements as may be reasonably necessary or desirable to effect the purpose of this Agreement and carry out its provisions.

14.13 Severability. In the event that any provision of this Agreement shall be held invalid or unenforceable by any court of competent jurisdiction, such holding shall not invalidate or render unenforceable any other provision hereof.

14.14 Captions. The article and section captions in this Agreement have been inserted as a matter of convenience and are not part of this Agreement.

14.15 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original of this Agreement and all of which together shall constitute one and the same instrument.

14.16 Independent Relationship. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one party for the act or failure to act of the other party. Neither party shall have any power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other or to bind the other party in any respect whatsoever. All activities undertaken by ETHYPHARM hereunder shall be that of an independent contractor.

14.17 Entire Agreement. This written Agreement, together with all exhibits, schedules and attachments hereto, constitutes the entire understanding between the parties hereto relating to the subject matter hereof and supersedes and replaces all prior and contemporaneous agreements relating thereto. No variation or modification of this Agreement or waiver of any of the terms or provisions hereof shall be deemed valid unless in writing and signed by both parties hereto.

14.18 Continued Obligation. During the pendency of any bona fide dispute, the parties shall continue to perform their respective obligations under this Agreement until such time as (a) the matter in dispute is finally resolved or (b) this Agreement is terminated in accordance with its terms.

14.19 Survival. The provisions of Sections 6, 7.7, 7.8, 7.9, 7.11, 11.2, 12.2, 13, 14.2, 14,7, 14.8, 14.9, 14.10, 14.11 shall survive and remain in effect after termination or expiration of this Agreement.

(Signature page follows.)

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

ETHYPHARM S.A.

By: _____
Gérard M. Leduc, General Manager

ETHYPHARM INDUSTRIES S.A.

By: _____
Gérard M. Leduc, President

RELIANT PHARMACEUTICALS, LLC

By: _____
Joseph Krivulka, President

Acceptance and acknowledgment of appointment by ETHYPHARM as its agent for service of process under Section 14.8 of this Agreement:

ETHYPHARM CORP.

By: _____
Hafid Touam, Vice President

**SIGNATURE PAGE TO DEVELOPMENT,
LICENSE AND SUPPLY AGREEMENT**

EXHIBIT A

Product Specifications

The Product will be manufactured according to the process outlined below. Specifications will be established during the course of development of the Product on the basis of the regulatory filing in France of a similar product manufactured by Ethypharm, the development plan as outlined in Exhibit B, cGMP standards, and Applicable Laws, including, without limitations, FDA regulatory requirements. This Exhibit A may be amended or changed from time to time as contemplated by the Agreement and shall be at all times conform to the provisions thereof.

Manufacturing Process for the Product

[***] [2 pages omitted]

[***]: Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT B

Product Development Program

[***] [2 pages omitted]

PHASE A—MANUFACTURING PROGRAM

TOPIC	EVENT	VALIDATION	DELIVERABLES	RESPONSIBLE PARTY	COMPLETION DATE	
					DRAFT	FINAL
[***]						

PHASE A—FORMULATION & MANUFACTURING DEVELOPMENT

TOPIC	EVENT	VALIDATION	DELIVERABLES	RESPONSIBLE PARTY	COMPLETION DATE	
					DRAFT	FINAL
[***]						

PHASE B—MANUFACTURING PROGRAM

TOPIC	EVENT	VALIDATION	DELIVERABLES	RESPONSIBLE PARTY	COMPLETION DATE	
					DRAFT	FINAL
[***]						

PHASE B—STABILITY PROGRAM

TOPIC	EVENT	VALIDATION	DELIVERABLES	RESPONSIBLE PARTY	COMPLETION DATE	
					DRAFT	FINAL
[***]						

PHASE B—SHIPPING PROGRAM

TOPIC	EVENT	VALIDATION	DELIVERABLES	RESPONSIBLE PARTY	COMPLETION DATE	
					DRAFT	FINAL
[***]						

[***]:Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT C

Cost Escalation Index

Minimum conventional salary fixed by the
Convention Nationale Collective de l'Industrie in France (class 6)

Minimum Salary for the Group 6A / SNIP

Minimum Salary for 169 hours

Point Number = 118

in FRF

		Constant Value		Point Value			
Year	**Month**	***Increase***	**New value**	***Increase***	**New value**	**Group 6A in FRF (1)**	**Global Increase**
1997	April	*1.2%*	6,535	*1.2%*	44.53	11,790	1.20%
	July	*0.8%*	6,587	*0.8%*	44.89	11,884	0.80%
	Total year						**2.01%**
1998	July	*1.7%*	6,699	*0.8%*	45.25	12,039	**1.30%**
1999	-	*0%*	6,699	*0%*	45.25	12,039	**0.00%**
2000	November	*3.3%*	6,920	*3.3%*	46.74	12,435	**3.30%**
2001	January	*1.0%*	6,989	*1.0%*	47.21	12,560	**1.00%**
	July	*0.5%*	7,024	*0.5%*	47.45	12,623	**0.51%**
	Total year						**1.51%**

Minimum Salary = Constant Value + Point value x Point Number

Minimum Salary for 151.67 hours:

3.3%	6,210	*3.3%*	41.95	11,160	**3.30%**
6.0%	6,583	*6.0%*	44.46	11,830	**6.00%**
0.5%	6,616	*0.5%*	44.69	11.869	**0.50%**
					6.53%

EXHIBIT D

ETHYPHARM MANUFACTURING COST CALCULATION

The purpose of this exhibit is to establish the direct manufacturing cost calculation methodology as required per Section 8.1 of this Agreement.

Ethypharm and Reliant agree that the basis for cost calculation shall be Ethypharm's direct manufacturing costs, which means only those cost elements that derive from actual inputs into the Product and which can be measured and objectively traced back to the manufacturing of the Product as defined in this agreement.

Direct manufacturing costs for the Product are: [***]

Reliant shall have the right to have the cost calculation audited and verified by an independent audit firm. In the event that the manufacturing cost as per this Exhibit D is found by the independent audit firm to be more than 10% lower than the cost calculated by Ethypharm, Ethypharm will pay for this audit and reimburse Reliant for the difference established by the audit. Reliant will pay for this audit if the verified manufacturing cost is within 10% of the Ethypharm's calculation.

In order to ensure rational and cost-effective materials purchasing practices, Reliant shall have the right to obtain 2 competitive bids for each of those materials used and for which Reliant believes the purchasing price is significantly above the market price. Bids will have to be based on same quality, quantity, regulatory & patent status. On the basis of these competitive bids an alternative materials cost will be established. In no event shall the materials cost as charged by Ethypharm exceed the average of the 2 competitive bids as obtained by Reliant plus [***]%.

[***]:Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

SCHEDULE 1.42

Patents

Ethypharm represents and warrants that it owns all rights to the following patents or pending applications:

- U.S. Patent No. 4,961,890 to J.F. Boyer
- U.S. Patent No. 4,800,079 to J.F. Boyer
- PCT No. WO 01/03693 to B. Criere *et al*.

In addition, Ethypharm represents and warrants that Ethypharm and its suppliers are fully enabled to manufacture, and are licensed to all applicable patents relevant to the manufacturing of, the Product, used excipients and the active ingredient fenofibrate at the locations chosen for such manufacturing.

Dates Referenced Herein *and* Documents Incorporated By Reference

This S-1/A Filing	***Date***	***Other Filings***
	5/7/01	
Filed On / Filed As Of	8/5/05	

Top List All Filings

Filing Submission - Alternative Formats (Word / Rich Text, HTML, Plain Text, SGML, XML, et al.)

EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

STATE OF FLORIDA by Attorney General Bill McCollum STATE OF ARIZONA by Attorney General Terry Goddard STATE OF ARKANSAS by Attorney General Dustin McDaniel STATE OF CALIFORNIA by Attorney General Edmund G. Brown, Jr. STATE OF CONNECTICUT by Attorney General Richard Blumenthal DISTRICT OF COLUMBIA by Interim Attorney General Peter J. Nickles STATE OF IDAHO by Attorney General Lawrence G. Wasden STATE OF IOWA by Attorney General Thomas J. Miller STATE OF KANSAS by Attorney General Stephen N. Six STATE OF MAINE by Attorney General G. Steven Rowe STATE OF MARYLAND by Attorney General Douglas F. Gansler COMMONWEALTH OF MASSACHUSETTS by Attorney General Martha Coakley STATE OF MICHIGAN by Attorney General Michael A. Cox STATE OF MINNESOTA by Attorney General Lori Swanson	Case No. 08-155

STATE OF MISSOURI)
by Attorney General Jeremiah (Jay) W. Nixon)
)
STATE OF NEVADA)
by Attorney General Catherine Cortez Masto)
)
STATE OF NEW YORK)
by Attorney General Andrew M. Cuomo)
)
STATE OF NORTH CAROLINA)
by Attorney General Roy Cooper)
)
STATE OF OHIO)
by Attorney General Marc E. Dann)
)
STATE OF OREGON)
by Attorney General Hardy Myers)
)
COMMONWEALTH OF PENNSYLVANIA)
by Attorney General Tom Corbett)
)
STATE OF SOUTH CAROLINA)
by Attorney General Henry McMaster)
)
STATE OF TEXAS)
by Attorney General Greg Abbott)
)
STATE OF VERMONT)
by Attorney General William H. Sorrell)
)
STATE OF WASHINGTON)
by Attorney General Rob McKenna)
)
STATE OF WEST VIRGINIA)
by Attorney General Darrell V. McGraw, Jr.)
)
Plaintiffs,)
v.)
)
ABBOTT LABORATORIES, FOURNIER)
INDUSTRIE ET SANTE, and)
LABORATOIRES FOURNIER, S.A.,)
) JURY TRIAL DEMANDED
Defendants.)

FIRST AMENDED COMPLAINT

The states of Florida, Arizona, Arkansas, California, Connecticut, Idaho, Iowa, Kansas, Maine, Maryland, Michigan, Minnesota, Missouri, Nevada, New York, North Carolina, Ohio, Oregon, South Carolina, Texas, Vermont, Washington, West Virginia, the Commonwealths of Massachusetts and Pennsylvania, and the District of Columbia (collectively "Plaintiff States"), by their Attorneys General, on behalf of and/or for the benefit of their respective citizens and government entities, complain against Defendants Abbott Laboratories ("Abbott") and Defendants Fournier Industrie et Sante and Laboratoires Fournier, S.A., (collectively "Fournier") as follows:

Nature of the Action

1. Plaintiff States seek injunctive relief, penalties, damages, disgorgement and restitution for the Defendants' unlawful monopolization of the fenofibrate market. Abbott and Fournier feared that competition from generic manufacturers would significantly decrease prices for fenofibrate drugs and dilute their TriCor monopoly profits when consumers and state purchasers switched to lower-priced generic drugs. Once generic competition began, Abbott and Fournier knew that sales of TriCor would decline significantly. As a result, they conspired to implement their anti-generic strategy.

2. TriCor is a brand-name prescription drug that uses the active ingredient, fenofibrate, to regulate triglyceride and cholesterol levels. TriCor and other fenofibrate drugs lower triglyceride levels, reduce low-density lipoprotein cholesterol ("LDL" or "bad cholesterol"), and increase the levels of high-density lipoprotein cholesterol ("HDL" or "good cholesterol"). Fenofibrate drugs are prescribed for patients with

hypercholesterolemia (high bad cholesterol), hypertriglyceridemia (high triglycerides), and mixed dyslipidemia (high bad cholesterol, high triglycerides, and low good cholesterol). TriCor is a maintenance drug that is generally prescribed for long-term cholesterol problems. Prescriptions for TriCor often provide numerous refills.

3. Since 1998, Abbott and Fournier have sold TriCor in the United States and have conspired to maintain monopoly power in fenofibrate drugs by excluding generic competition through improper means. As a result, consumers and state governments have paid more for fenofibrate drugs while Abbott and Fournier enjoyed annual revenues from TriCor sales that exceeded $1 billion.

4. Abbott and Fournier conspired to monopolize and implemented an anti-generic strategy by orchestrating a scheme that involved:

a) Obtaining multiple patents through inequitable conduct, listing these patents with the Food and Drug Administration, knowing they were obtained improperly, and then filing sham patent litigation without a reasonable basis to believe those patents were enforceable and/or were infringed, for the purpose of delaying generic entry and foreclosing competition in the market; and

b) Forcing the market to convert to new formulations before generic entry by:

i. Reformulating TriCor with only minor changes to a form and dosage strength, which did not provide any significant new clinical benefit;

ii. Creating an artificial product differentiation to be used as a marketing tool to convince physicians to stop writing prescriptions for the old formulation and to write prescriptions only for the new formulation;

iii. Stopping promotion and sales of the previous TriCor formulation upon the introduction of the new formulation;

iv. Removing the old TriCor formulation from the market, so as to make it commercially unavailable by the time a generic competitor could enter the market, and

v. Interfering with the normal and customary channels of distribution used by generics to compete in the market.

5. Abbott's and Fournier's anti-generic strategy was successful. When the patent litigations against the generic manufacturers of fenofibrate concluded, the old formulations of TriCor were no longer commercially available for any entering generic manufacturer to compete against. Abbott and Fournier have executed this on-going scheme to convert the fenofibrate market twice: first in 2001-2002, when they converted the market from TriCor 200mg capsules to TriCor 160mg tablets; and then in 2004-2005, when they converted the market from TriCor 160mg tablets to TriCor 145mg tablets. Moreover, Abbott and Fournier plan to continue their reformulation strategy for TriCor.

6. Abbott's and Fournier's anti-generic scheme was designed and undertaken for the purpose of, and had the intended effect of, preventing generic substitution, foreclosing competition, and denying consumer choice.

7. As a result of Abbott's and Fournier's anticompetitive conduct, consumers and state governments have been and continue to be deprived of the lower prices that generic competition brings, while Abbott and Fournier have continued to reap monopoly profits from the sale of TriCor.

8. Furthermore, Abbott's and Fournier's conduct has been deceptive or unconscionable, has included unfair practices and/or unfair methods of competition, or has been otherwise unlawful under the consumer protection laws of certain of the Plaintiff States and has caused harm to those Plaintiff States, their governmental entities

and consumers by forcing them to pay more for fenofibrate than they otherwise would have in a competitive market.

Jurisdiction & Venue

9. Under 28 U.S.C. §§1331 and 1337, this Court has subject matter jurisdiction over the federal antitrust claims under the Sherman Act. This Court also has supplemental jurisdiction over the state law claims under 28 U.S.C. §1367 because those claims are so related to the federal claims that they form part of the same case or controversy. The exercise of supplemental jurisdiction avoids unnecessary duplication and multiplicity of actions and is in the interests of judicial economy, convenience, and fairness.

10. Venue is proper in this district under 15 U.S.C. §22 and 28 U.S.C. §1391(b) and (c). Each Defendant resides, transacts business, committed an illegal or tortious act, or is found in this district, and a substantial part of the events giving rise to the claims arose in this district.

Parties

11. Defendant Abbott Laboratories is a corporation organized, existing and doing business under the laws of the State of Illinois. Its office and principal place of business is located at 100 Abbott Park Road, Abbott Park, Illinois. Abbott is engaged principally in the development, manufacture, and sale of pharmaceuticals and health care products and services throughout the United States.

12. Defendant Fournier Industrie et Sante is a French corporation headquartered at 42, Rue de Longvic, 21300 Chenove, France. Formerly known as

Fournier Innovation et Synergie, Fournier Industrie et Sante was the holding company for a conglomerate of French and international companies.

13. Defendant Laboratoires Fournier, S.A. is a wholly-owned French subsidiary of Fournier Industrie et Sante and is also headquartered at 42, Rue de Longvic, 21300 Chenove, France. Fournier Industrie et Sante and Laboratoires Fournier, S.A. collaborated with Abbott for regulatory approval, production, and sale of TriCor in the United States.

14. Plaintiff States bring this action by and through their Attorneys General: (a) in their sovereign capacities as representatives and/or for the benefit of natural persons and/or as parens patriae of natural persons under state or federal law; (b) as parens patriae in their sovereign capacities to redress injury to their respective states' general economies; (c) in their sovereign and/or proprietary capacities, which may include state departments, bureaus, agencies, political subdivisions, and other instrumentalities as purchasers (either directly, indirectly, or as assignees), based on purchases of TriCor; and/or (d) as the chief law enforcement agency or other enforcement agency of each state to the extent that violations of the states' antitrust and consumer protection laws and regulations are alleged herein.

Relevant Market

15. The relevant product market is any drug with fenofibrate as the active ingredient. Fenofibrate has a unique therapeutic effect on cholesterol and triglyceride levels and differs from other lipid-regulating drugs such that they are not reasonably interchangeable. The fenofibrate market includes TriCor and generics that can be substituted.

16. The relevant geographic market is the United States.

17. At all relevant times, Abbott and Fournier enjoyed a market share in the United States fenofibrate market between 90% and 100%.

Trade and Commerce

18. Since May 1998, TriCor has been sold in interstate commerce throughout the United States.

19. TriCor has been transported across state lines and has been sold in each of the Plaintiff States. Abbott's and Fournier's unlawful activities alleged in this Complaint have occurred in and have had a substantial effect upon interstate commerce. Abbott's and Fournier's annual revenues for TriCor sold in the U.S. have surpassed $1 billion.

Factual Background

I. The Hatch-Waxman Act

20. The manufacture and commercial sale of pharmaceutical drugs are regulated by the Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301, *et seq*. The manufacturer of a new drug must submit a new drug application ("NDA") that demonstrates, among other things, a drug's safety, clinically-proven effectiveness, composition, and patent coverage.

21. To speed the entry of generic drugs and to facilitate price competition with branded drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). Under the Hatch-Waxman Act, generic drug manufacturers may receive FDA approval for generic drugs without replicating costly and time-consuming clinical trials. Instead, a generic drug manufacturer may submit an

abbreviated new drug application ("ANDA") and incorporate data, such as clinical studies, that the NDA filer submitted to the FDA. To be approved, an ANDA must demonstrate that the generic drug has the same active ingredients as, is pharmaceutically equivalent to, is bioequivalent to, and has the same labeling as the previously approved drug. The FDA publishes a list of all approved drugs and therapeutically equivalents in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book").

22. The Orange Book also lists all patents, if any, covering an approved drug. If the ANDA applicant seeks approval to market a drug before the expiration date of one or more of the patents listed in the Orange Book, the ANDA applicant must certify that each patent "is invalid, unenforceable or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. §355 (j)(2)(A)(vii)(IV). This is commonly referred to as a Paragraph IV Certification. An ANDA applicant must also notify the patent owner and NDA holder of the Paragraph IV Certification and provide a written statement of the reasons each patent is not infringed, is invalid, or is unenforceable.

23. Upon receipt of the Paragraph IV notice, a patent holder or NDA holder that believes the generic will infringe a valid and enforceable patent may sue the ANDA applicant for patent infringement. If such an action is brought within 45 days from receipt of that notice, the FDA is precluded from granting final approval of the ANDA until the earlier of: 1) 30 months from the receipt of the Paragraph IV notice; 2) the date on which the court holds the patent is invalid, not infringed, or unenforceable; or 3) the date on which the case is withdrawn, discontinued, dismissed, or otherwise terminated by

the patent holder or NDA holder. This time period is often referred to as a "30-month stay." If the patent holder or NDA holder does not file a patent infringement action within the 45-day period, the FDA may grant final approval of the ANDA, if the FDA's other regulatory requirements are satisfied.

II. Generic Substitution

24. In most States and under most health plans, a pharmacist may substitute a generic drug for a prescribed brand name drug when the FDA has given the generic drug an AB rating to that branded drug.

25. An AB rating requires the generic drug to be both pharmaceutically equivalent and bioequivalent to the branded drug. The FDA considers a drug product to be a pharmaceutical equivalent if the drug contains the same active ingredient; is of the same dosage, form, and route of administration; and is identical in strength. The FDA considers a drug product bioequivalent if the drug shows comparable bioavailability, which is the rate and extent that the active ingredient is absorbed from the drug product when studied under similar experimental conditions.

26. Once the FDA approves an ANDA for a generic drug and determines it is AB-rated to the branded drug, state laws govern how the generic drug may be substituted for the brand name drug prescribed by physicians. Generally, state laws permit pharmacists to substitute an AB-rated generic drug for the brand name drug, unless there is a doctor or patient request otherwise.

III. Insurance Coverage and Patient Co-Pays

27. While some patients are responsible for the full cost of prescription drugs, health plans, insurers and other third-party payors pay most of the direct costs of acquiring prescription drugs and use various means to control costs, including a formulary. A formulary is a list of preferred drugs that a payor predetermines that it will cover for its enrollees. Formularies can be open, closed or incentive-based. An incentive-based formulary generally tiers the drugs on the formulary by preference and charges enrollees the lowest co-pay for drugs from the first tier.

28. Healthcare insurers and other third parties who pay for prescription medications use private databases, like First DataBank's National Drug Data File ("NDDF"), to access prescription drug descriptions and pricing data, to identify AB-rated drugs and to obtain other information about FDA-approved drugs. For example, the NDDF uses a "Generic Indicator" code to identify whether a drug is a "single-source product" (i.e. the drug is supplied by only one company), or whether it is a "multi-source product" (i.e. the drug is supplied by multiple companies). Identifying a drug as a "multi-source product" indicates that an AB-rated generic drug is available.

29. Brand-name drug manufacturers can manipulate the NDDF to restrain generic competition. For example, if a manufacturer's reference number or NDC number for the branded drug is removed from the NDDF, the branded drug is no longer listed in that database. The branded drug would no longer be linked to any generic that obtains an AB-rating to the branded drug. A later-listed generic then would be identified as a single source product, causing insurers and other payors to classify the intended generic drug as

a branded product and either not cover it or charge patients higher co-pays for it. The result is that it is less likely that the generic drug will be either dispensed or purchased.

30. Similarly, the removal of the reference to the branded drug and/or the NDC number would impede a pharmacist's ability to advise the consumer that an AB-rated generic drug is available, or to contact the consumer's physician to suggest the physician re-write a prescription for that generic. Thus, manufacturers can manipulate the availability of important information that third-party payors and pharmacists frequently rely on, causing normal channels of distribution for generic manufacturers to be disrupted, if not entirely foreclosed.

Abbott's and Fournier's Anticompetitive Conduct

I. Abbott's and Fournier's First TriCor Switch

A. Abbott and Fournier Developed an Anti-Generic Strategy

31. Fournier received FDA approval in 1993 for a fenofibrate drug called Lipidil. Fournier did not market Lipidil in the United States so it sought and found an experienced, United States-based collaborator: Abbott. In January 1998, Abbott and Fournier reached an agreement under which Fournier licensed to Abbott the rights to sell Fournier's fenofibrate drug in the United States. Since then, Abbott and Fournier have been collaborators in developing and marketing fenofibrate drugs in the United States under the brand name TriCor.

32. In February 1998, Fournier received FDA approval to sell 67mg TriCor capsules to treat high triglyceride levels, and later Abbott received FDA approval to sell TriCor capsules at 134mg and 200mg strengths (collectively "TriCor 200mg Capsules").

33. Abbott and Fournier expected that generic competition could occur within two to three years after the launch of TriCor 200mg Capsules. They feared that if an AB-rated generic fenofibrate drug reached the market, substitution would occur and TriCor's market share would fall significantly.

34. Shortly after Abbott introduced TriCor in the United States, Abbott and Fournier began developing a sophisticated scheme to unlawfully thwart generic competition and maintain their monopoly in the fenofibrate market. Abbott and Fournier executives discussed how to exclude and defeat generic competition for TriCor. They agreed that the number one priority was to develop an anti-generic strategy and changing TriCor's formulation was critical to forestall generic competition.

35. Abbott and Fournier agreed to an anti-generic strategy that included enforcing multiple patents with the knowledge that the patents were not infringed. This strategy was intended to generate enough time to introduce a reformulated TriCor product so that any generic competition would be foreclosed. Abbott and Fournier used the 30-month stay triggered by their patent litigation to ensure that they had sufficient time to launch the new formulation, to force the market to convert to it and to withdraw the prior formulation from the market. This left consumers, physicians, pharmacists and third-party payors with no choice but to use the reformulated product. Abbott and Fournier planned to switch the market to a reformulated TriCor product every few years, thereby creating a "moving target" for generic manufacturers.

B. Abbott and Fournier Used Patent Litigation to Create Time to Reformulate TriCor

36. Fournier obtained U.S. Patent No. 4,895,726 ("'726 Patent"), which was listed in the FDA's Orange Book for TriCor 200mg Capsules.

37. In December of 1999, a generic manufacturer, Novopharm Ltd., which was later acquired by Teva Pharmaceuticals USA, Inc., (collectively known as "Teva") filed an ANDA with the FDA seeking approval of a generic version of TriCor 200mg Capsules. Pursuant to the Hatch-Waxman Act, Teva submitted a Paragraph IV notice for each strength to Abbott stating that its generic capsules did not infringe the '726 Patent. As part of their anti-generic scheme, after receiving Teva's three Paragraph IV notifications, Fournier and Abbott filed three baseless patent infringement suits against Teva claiming infringement of the '726 Patent, triggering a 30-month stay and delaying the FDA's approval of Teva's generic fenofibrate capsules.

38. In May of 2000, Impax Laboratories, Inc. ("Impax") also filed an ANDA for generic fenofibrate capsules and submitted a Paragraph IV Certification stating that its formulation for a generic capsule did not infringe the '726 Patent. After receiving Impax's Paragraph IV notice, Fournier and Abbott filed a baseless patent infringement suit against Impax claiming infringement of the '726 Patent, triggering a 30-month automatic stay and delaying the FDA's approval of Impax's generic fenofibrate capsules.

39. The claims contained within the '726 Patent require, among other things, that fenofibrate be co-micronized with a solid surfactant in the absence of any excipients. Because the '726 Patent claims require co-micronization of the fenofibrate and solid surfactant in the absence of excipients, and Teva's and Impax's Paragraph IV notifications expressly indicated they did not use that process, Abbott and Fournier had

no basis to sue nor to continue to prosecute their suits against Teva and Impax by asserting that their capsule ANDAs infringed the '726 Patent. These suits began a pattern of Abbott and Fournier filing baseless patent lawsuits against Teva and Impax.

40. On March 19, 2002, the District Court granted summary judgment for Teva finding it did not infringe the '726 Patent. Two weeks later the FDA granted final approval of Teva's ANDA for two of the capsule strengths, and by September 2002, the FDA had granted approval for all strengths of Teva's generic fenofibrate capsules. Summary judgment of noninfringement was also later granted in favor of Impax. The Court of Appeals for the Federal Circuit later affirmed the summary judgment in favor of Teva, stating that "there can be no dispute that fenofibrate and a solid surfactant are not 'co-micronized' as that term is used in the '726 Patent."

41. Abbott's and Fournier's purpose in filing and maintaining these patent infringement suits against Teva and Impax, both separately and as part of their overall scheme, was to trigger a series of 30-month automatic stays to delay FDA approval of and Teva's and Impax's entry into the market with a generic version of TriCor capsules to interfere with their ability to introduce generic fenofibrate capsules and to compete with TriCor.

C. Abbott and Fournier Forced the Market to Switch to TriCor 160mg Tablets

42. During the 30-month stays, triggered by their lawsuits, Abbott and Fournier successfully forced the market to switch to TriCor tablets before competition from generic fenofibrate capsules could begin to erode their monopoly position in the fenofibrate market.

1. The Reformulation: Abbott and Fournier Reformulated TriCor to Avoid Competition from an AB-Rated Drug and to Justify their Marketing Campaign

43. While delaying generic entry by filing their patent infringement litigation, Abbott and Fournier executed the rest of their strategy to convert the market to a new formulation of TriCor.

44. Abbott and Fournier executed this strategy by making minor changes to TriCor 200mg Capsules, which had no new clinical benefit, to facilitate marketing the next formulation of TriCor to doctors, pharmacists, health insurers and third-party payors.

45. During the FDA review of Abbott's NDA, Abbott submitted data to show that the formulation in TriCor 160mg Tablets could raise HDL, or good cholesterol levels. The FDA approved this additional indication for HDL, permitting Abbott to include it on the label for TriCor 160mg Tablets and in their marketing materials.

46. In reality, TriCor 160mg Tablets and TriCor 200mg Capsules had the same effect on HDL. Abbott's data demonstrating this effect came from the same Fournier studies previously submitted to the FDA for TriCor 200mg Capsules. This HDL indication could have been sought for TriCor 200mg Capsules. Instead, Abbott and Fournier chose to delay that request to artificially differentiate TriCor 160 mg Tablets from TriCor 200mg Capsules.

47. TriCor 160mg Tablets were not AB-rated to TriCor 200mg Capsules or any generic fenofibrate capsules. While the reformulated TriCor 160mg Tablets were bioequivalent to TriCor 200mg Capsules, the tablets had a different dosage and a different form and were not pharmaceutical equivalents. This change in dosage and form precluded an AB rating for TriCor 160mg Tablets and TriCor 200mg Capsules or any

AB-rated generic 200mg capsules. As a result, pharmacists could not substitute TriCor 160mg Tablets with any generic fenofibrate capsules, including those for which Teva and Impax would obtain FDA approval.

48. While Abbott's new formulation thwarted the AB-rating, the FDA did not recognize these changes as clinically or therapeutically significant. Abbott's own managers and scientist viewed the capsule and tablet formulations to be clinically and therapeutically equivalent. Moreover, Abbott priced TriCor 160mg Tablets the same as TriCor 200mg Capsules, reflecting that Abbott viewed them as clinically equivalent.

49. In switching from capsules to tablets, Abbott and Fournier changed TriCor's labeling, but not its efficacy and safety for consumers. Abbott and Fournier could promote an indication for raising HDL levels as "new" but, in fact, the effect was not "new" because there was no demonstrated change in efficacy between TriCor 200mg Capsules and TriCor 160mg Tablets.

2. The Switch: Abbott Launched a Marketing Blitz

50. A cornerstone of Abbott's and Fournier's marketing strategy was to convince physicians, health insurers, pharmacists and consumers that TriCor 160mg Tablets had an advantage over TriCor 200mg Capsules. The "new" HDL indication on the label for TriCor 160mg Tablets allowed Abbott to have a new marketing spin for them. A majority of physicians were already aware that TriCor—in capsules or tablets—could raise HDL levels. As a result, the HDL label change was expected to have little-to-no impact on Abbott's sales of TriCor 160mg Tablets.

51. Abbott and Fournier launched an aggressive marketing campaign to promote TriCor 160mg Tablets to physicians, pharmacists, insurers and third-party

payors. Abbott's sales force canvassed key TriCor prescribers to convince physicians to write all prescriptions and refills for TriCor 200mg Capsules for the newly reformulated TriCor 160mg Tablets.

52. Abbott was concerned that if insurers and other third-party payors thought the switch to TriCor 160mg Tablets was a strategy to deter generic competition, they might not place TriCor 160mg Tablets in a preferred position in their formularies. Abbott's sales force thus took extra measures to meet with insurers and payors to convince them to list the reformulated TriCor 160mg Tablets as a preferred drug on the formulary.

53. Additionally, as part of Abbott's and Fournier's plan, they sent Abbott's sales force to retail pharmacies to discourage them from stocking any fenofibrate drugs other than TriCor 160mg Tablets. Defendants undertook this tactic to deter generic entry and retain their monopoly on fenofibrate.

54. To further persuade physicians and pharmacists to prescribe and stock TriCor 160mg Tablets, Abbott informed them that they were discontinuing TriCor 200mg Capsules.

3. The Forced Conversion: Abbott and Fournier Discontinued Sales and Production of TriCor 200mg Capsules

55. As part of their strategy to rapidly convert TriCor purchasers from capsules to tablets prior to the entry of generic competition, Abbott and Fournier planned to discontinue all production, sales and promotion efforts for TriCor 200mg Capsules, and instead to focus all sales and promotional efforts on TriCor 160mg Tablets.

56. To accelerate the switch from capsule to tablet formulations, Fournier stopped manufacturing TriCor 200mg Capsules. At the same time, Abbott stopped taking orders and began withdrawing the Capsules from the market.

4. The Purge: Abbott Reclaimed TriCor 200mg Capsules

57. In addition to ceasing sales, Abbott and Fournier sought to ensure that the existing inventory of TriCor 200mg Capsules at wholesalers' warehouses and/or on pharmacy stores' shelves was removed so that neither refills nor new prescriptions could be filled due to lack of supply.

58. Abbott sought to recover existing inventories of TriCor 200mg Capsules in an effort to purge the market of TriCor 200mg Capsules prior to any generic entry. Abbott and Fournier took this extra step because they realized that if TriCor 200mg Capsules were available, especially for refills, there could be no forced conversion to TriCor 160mg Tablets.

59. Abbott's and Fournier's plan was to contact wholesalers and large retailers and to offer to exchange TriCor 200mg Capsules for the reformulated TriCor 160mg Tablets. Abbott's plan was to accept capsules in exchange for tablets as well as credits. In doing so, Abbott deviated from its standard return policy in order to expedite the removal of TriCor 200mg Capsules from the market. After recovering TriCor 200mg Capsules, Abbott destroyed the capsules.

60. Abbott's and Fournier's forced conversion strategy was successful. By the end of February 2002, Abbott had killed TriCor 200mg Capsules.

5. The Final Nail: Abbott and Fournier Interfered with the Normal and Customary Methods Generics Use to Compete

61. By effectively purging the market of TriCor 200mg Capsules, Abbott and Fournier prevented pharmacists from substituting generic fenofibrate capsules, thereby effectively forcing the market to TriCor 160mg Tablets.

62. To further protect their fenofibrate monopoly against generic competition, Abbott and Fournier also sought to eliminate incentives for consumers to ask physicians to re-write TriCor prescriptions for capsules so generic fenofibrate capsules could be dispensed. Abbott accomplished this by manipulating a dominant source of information relied upon by the medical community: First DataBank's NDDF. By April 2002, shortly after Abbott had completed the switch to tablets, but before the generic capsules became available, Abbott instructed First DataBank to delete the NDC number for all TriCor capsules in its NDDF database. The removal of the reference for TriCor 200mg Capsules, including its NDC number, prevented pharmacists from identifying any AB-rated generic substitute in First DataBank's NDDF. Thus, due to Abbott's manipulation of the NDC number for TriCor 200mg Capsules in the NDDF, when Teva launched generic fenofibrate capsules in mid-2002, they were the only fenofibrate capsule listed in the NDDF and were coded as a single-source drug, not as a generic.

63. As a single-source drug in the NDDF, Teva's fenofibrate capsules generally were not afforded the preferred formulary status given generic drugs. Some insurers did not add Teva's generic capsules to their drug formularies and refused to pay for them at all. Other health insurers charged a higher co-pay than typically charged for a generic. As a result, Abbott prevented incentives for patients to request their TriCor 200mg Capsule prescriptions be rewritten for Teva's generic capsules.

64. With no opportunity to substitute TriCor prescriptions and scant incentive for patients or pharmacists to purchase generic fenofibrate capsules, there was little demand for generic fenofibrate capsules. Not surprisingly, potential manufacturers of generic fenofibrate capsules had little interest in entering the market.

D. Abbott's and Fournier's Anti-Generic Strategy was Successful

65. Abbott's and Fournier's efforts to force the market to convert were successful. By March 2002, most prescriptions for TriCor were for TriCor 160mg Tablets.

66. As a result, Abbott's and Fournier's reformulation and forced conversion strategy succeeded in thwarting generic fenofibrate entry. While most generic launches capture a large percentage of the market within weeks, when Teva launched generic fenofibrate capsules in mid-2002, Abbott and Fournier had already switched the market. As a result, more than a year after Teva's generic capsules came to market, generic fenofibrate drugs accounted for fewer than 2% of all fenofibrate prescriptions in the United States. Moreover, Impax, after obtaining FDA approval for its fenofibrate capsule, which were AB-rated to TriCor 200mg Capsules, never attempted to enter the market.

67. Substitution laws did not allow pharmacists to substitute a generic capsule to fill a prescription written for TriCor 160mg Tablets. The outcome was that purchasers, including consumers, state governments, and third-party payors were required to pay supracompetitive prices for TriCor 160mg Tablets and effectively denied the cost advantages of a competing generic drug.

II. Abbott's and Fournier's Second TriCor Switch

68. Even as Abbott and Fournier prevented competition from generic fenofibrate capsules, they also conspired to extend their anti-generic strategy to defeat anticipated generic competition for TriCor 160mg Tablets.

69. Abbott and Fournier undertook the same strategy they used to defeat entry of generic fenofibrate capsules. They improperly obtained several patents, and knowing these patents were unenforceable, submitted them to the FDA to be listed in the Orange Book. Then, Abbott and Fournier filed baseless patent infringement litigation to obtain 30-month stays barring FDA approval of the generics' ANDAs. During those stays, Abbott launched a reformulated TriCor product, and followed that launch with a market switch from TriCor 160mg Tablets to the reformulated TriCor 145mg tablets. Abbott also reclaimed any remaining TriCor 160mg Tablets as quickly as possible, so as to complete the conversion of the fenofibrate market before entry of any generic 160mg tablets. Finally, Abbott caused any reference to TriCor 160mg Tablets, including the NDC number, to be deleted, interfering with the normal and customary channels of distribution used by generic competitors. As a result, when the patent-based tablet litigation resulted in summary judgment for the generic manufacturers and was otherwise dismissed by Abbott and Fournier, terminating the 30-month stay blocking FDA approval of the ANDAs, there were no commercially available TriCor 160mg Tablets remaining.

A. The Stamm Patents Were Improperly Obtained

70. Fournier filed and prosecuted the applications for U.S. Patent Nos. 6,074,670 ("'670 Patent"), 6,277,405 ("'405 Patent"), 6,589,552 ("'552 Patent"), and

6,652,881 ("'881 Patent") (collectively, "Stamm Patents"), and communicated with Abbott concerning the prosecution of the Stamm Patents before the PTO.

71. Fournier committed inequitable conduct before the PTO by intentionally failing to disclose highly material data in the Stamm applications and supporting declarations, the omission of which caused the data presented to be misleading. Moreover, in response to the PTO's initial determination that the Stamm Patents were unpatentable due to the prior art, including its own '726 Patent, Fournier intentionally and knowingly relied on the misleading data to argue that the applications were patentable due to superior and unexpected dissolution rates. Fournier knew that the dissolution rates of the various fenofibrate compositions being claimed in the applications for the Stamm Patents were critical to the patentability of those compositions.

72. In its applications for each of the Stamm Patents, Fournier represented to the PTO that the fenofibrate formulations had "unexpectedly" faster dissolution rates than that of earlier fenofibrate products and patents, including its own '726 Patent. Fournier represented to the PTO that the dissolution and bioavailability of fenofibrate compositions created in accordance with the '726 Patent were "incomplete due to the poor hydrosolubility of fenofibrate." In contrast, Fournier claimed that the Stamm formulations achieved a "superior" dissolution of greater than "10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes."

73. To convince the PTO that the Stamm formulations dissolved faster than the earlier '726 Patent, Fournier presented the PTO with tests that purported to compare the dissolution of two 100mg tablets of the Stamm formulations with TriCor 200mg Capsules made using the '726 Patent.

74. Fournier represented to the PTO that the test results "clearly showed the composition, according to the [Stamm] invention, has a dissolution profile which is distinctly better [faster] than that of the prior art compositions."

75. But at the time that Fournier made these representations to the PTO, Fournier had other data, which it did not disclose to the PTO, showing that TriCor 200mg Capsules had faster dissolution rates than were represented. Some of the new data showed that TriCor 200mg Capsules dissolved just as fast, if not faster, than the supposedly "unexpectedly superior" dissolution results claimed in the Stamm applications.

76. Specifically, Fournier failed to disclose to the PTO two sources of data that contradicted its assertions of "unexpectedly superior" dissolution results. First was a May 30, 1997, memorandum by a Fournier employee, Pascale Blouquin, ("Blouquin Memo") that revealed dissolution tests performed pursuant to the '726 Patent. The Blouquin Memo reported dissolution results of Lipanthyl 200M (later marketed as TriCor 200mg Capsules) in a medium of .025 sodium lauryl sulfate that were even faster than dissolution results presented to the PTO in the Stamm applications. Second, Fournier documents also contained dissolution data for TriCor 67mg capsules that were as fast as the dissolution rates claimed in the Stamm applications, except for the 5 minute interval. None of these tests were disclosed at the time Fournier was prosecuting the Stamm Patent applications.

77. Additionally, a declaration submitted by Philippe Reginault, a Fournier employee, in support of the Stamm applications, also failed to disclose these sources. Reginault's sworn declaration, submitted in support of the Stamm Patent application that

resulted in the issuance of the '881 Patent, failed to disclose data despite his affirmation that he knew and understood that he had a duty to disclose all material information when providing submissions to the PTO during prosecution of a patent application.

78. As Fournier's director of pharmaceutical development between 1988 and 2002, Reginault was intimately involved in Fournier's fenofibrate formulation and analytical development projects. In 2002, Reginault became Fournier's director of pharmaceutical technologies evaluation and continued his involvement with Fournier's fenofibrate projects. Moreover, it was Reginault who was instrumental to Fournier using patents to delay generic competition and was Fournier's primary technical contact with Abbott.

79. The PTO initially rejected all of the Stamm Patent applications on the grounds that the fenofibrate formulations claimed in those applications were too similar to and not patentably different from the formulations claimed in the '726 Patent and other earlier patents. Fournier disputed the PTO's rejections, citing and relying on the misleading data to argue that the formulations in the Stamm Patent applications had a surprisingly and unexpectedly faster dissolution rate, and hence should be patented. Fournier repeatedly cited in each Stamm Patent application the misleading comparisons of the dissolution rates of the earlier fenofibrate products with those being claimed in the "new" invention. Fournier continued to withhold the material data showing faster dissolution rates for earlier products and patents throughout the prosecution of the Stamm Patents to overcome rejections based on the '726 Patent and other earlier patents. At no time during the prosecution of the Stamm Patents did Fournier disclose the data that was less favorable to, and indeed contradicted, its argument that the Stamm Patents produced

a formulation with dissolution results superior to those reflected in earlier patents. Instead, Fournier continued to rely on the misleading data in arguing that the Stamm applications were patentable and non obvious.

80. In issuing the Stamm Patents, the PTO relied upon Fournier's continued use of and reference to the misleading data on unexpected, superior dissolutions of the Stamm formulations.

81. The data withheld by Fournier and Reginault was highly material both in view of (1) Fournier's original arguments that the Stamm Patents were different from the prior art in the '726 Patent and other patents due to an allegedly faster dissolution profile in each of the four Stamm Patents, and (2) Fournier's other arguments made during prosecution to overcome rejections based on prior art, including the '726 Patent.

82. The material information was withheld and the misleading declaration was submitted by Fournier and Reginault with intent to deceive the PTO. Fournier and Reginault made misleading representations and withheld highly material information with the intent and objective of inducing the PTO to issue the Stamm Patents. Each of the Stamm Patents is tainted by inequitable conduct and thus none of the Stamm Patents are enforceable.

83. Fournier's overall purpose in obtaining each of the Stamm Patents was to prohibit or delay generic competition for TriCor. Fournier's repeated misstatements and failures to disclose highly material information was part of Fournier's and Abbott's single, overall coordinated scheme, and evidenced their intent to deceive the PTO for the purpose of wrongfully excluding competition.

84. Fournier and Abbott intended to and did deceive the PTO because they knew that by obtaining any patent that claimed fenofibrate, they could improperly submit those patents to the FDA to be listed in the Orange Book. This would force any ANDA filer to file a Paragraph IV Certification, opening the door to infringement litigation that would trigger a 30-month stay of the FDA's approval of the ANDA, regardless of the strength of the patent or the outcome of the patent litigation.

B. Abbott and Fournier Abused the Hatch-Waxman Regulatory Scheme by Having Unenforceable Patents Listed in the Orange Book

85. The Stamm Patents were issued by the PTO at various times beginning on June 13, 2000, through November 25, 2003. Upon issuance, each Stamm Patent was listed in the Orange Book. Because Abbott and Fournier knew that the Stamm Patents were unenforceable, they unlawfully impeded generic entry by listing each of the Stamm Patents in the FDA's Orange Book.

86. Because of the Orange Book listing, Teva and Impax were required to file ANDAs with Paragraph IV Certifications, asserting that each patent was unenforceable, invalid or not infringed by their generic fenofibrate tablet. Abbott and Fournier intended to and knew that by listing the unenforceable Stamm Patents in the Orange Book, Teva and Impax and other potential generic entrants would be required to file Paragraph IV Certifications as to each of the Stamm Patents. They also knew that any infringement litigation would automatically trigger multiple 30-month stays preventing FDA approval of Teva's and Impax's ANDA applications for generic fenofibrate tablets.

87. The listing of the Stamm Patents in the Orange Book was in furtherance of Abbott's and Fournier's overall scheme to monopolize and block generic competition in

the fenofibrate market. As a result of the wrongful listing of the Stamm Patents in the Orange Book, Abbott was able to obtain multiple 30-month stays on the FDA's approval for generic 160mg fenofibrate.

88. Obtaining several of the Stamm Patents by inequitable conduct was a component of Abbott's and Fournier's overall anticompetitive scheme. Standing alone, having the unenforceable Stamm Patents listed in the Orange Book was also a wrongful and unreasonable restraint on trade.

C. Abbott's and Fournier's Lawsuits were Baseless as the Stamm Patents were Unenforceable and they had No Reasonable Basis to Believe there was Infringement

1. The Tablet Lawsuits

89. Less than a year after Abbott and Fournier launched TriCor 160mg Tablets, generic manufacturers began filing ANDAs with the FDA seeking approval to launch generic versions of fenofibrate tablets. Along with filing the ANDAs, the generic manufacturers certified that their products did not infringe the '726, '670 and '405 Patents that Abbott and Fournier had listed in the FDA's Orange Book for its TriCor 160mg Tablet.

90. After Teva and Impax provided their Paragraph IV notices, Abbott and Fournier commenced three lawsuits against Teva and Impax in the District of Delaware (Civil Action No. 02-1512 filed on October 4, 2002; Civil Action 03-120 filed on January 23, 2003; and Civil Action No. 03-0288 filed on March 14, 2003) ("Original Tablet Lawsuits"), alleging that Teva infringed the '726, '670 and '405 Patents and that Impax infringed the '670 and '405 Patents. These suits triggered 30-month stays of the FDA's approval of Teva's and Impax's ANDAs.

91. In July of 2003, the PTO granted Fournier a new patent, the 6,589,552 ("'552 Patent"), which was a continuation of the '670 and '405 Patents. Abbott and Fournier promptly listed the '552 Patent in the Orange Book.

92. Teva and Impax then submitted new Paragraph IV Certifications for the '552 Patent and notified Abbott and Fournier that their ANDAs did not infringe the '552 Patent.

93. Starting in August of 2003, Abbott and Fournier filed additional tablet patent infringement lawsuits against Teva and Impax in the District of Delaware, including Civil Action No. 03-847 on August 29, 2003, and Civil Action No. 03-890 on September 22, 2003, alleging that their respective requests to the FDA for approval of their Tablet ANDAs infringed the '552 Patent ("'552 Lawsuits").

94. Again, Abbott's and Fournier's newly filed '552 Lawsuits triggered additional 30-month stays that prohibited the FDA from granting final approval of Teva's or Impax's Tablet ANDAs.

95. In November of 2003, Fournier was granted yet another patent from the Stamm Patent applications, U.S. Patent No. 6,652,881 ("'881 Patent") which Abbott promptly listed in the Orange Book.

96. Teva and Impax then submitted Paragraph IV notices for the '881 patent and, in response, Abbott and Fournier filed yet another round of tablet patent infringement lawsuits in the District of Delaware against Teva and Impax including Civil Action no. 04-0047 on January 22, 2004, and Civil Action no. 04-0048 on January 22, 2004 ("'881 Lawsuits").

2. All the Tablet Lawsuits were Baseless and Brought for the Purpose of Preventing Generic Competition, and all were Ultimately Dismissed

97. Each and every lawsuit brought by Abbott and Fournier asserting infringement of the Stamm Patents by Teva's and Impax's tablet formulations (the "Tablet Litigation") were baseless because Fournier obtained all of the Stamm Patents through inequitable conduct as described supra. Thus, at the time that Abbott and Fournier filed each of their infringement actions enforcing all of the Stamm Patents, and/or during the time that they maintained these suits, they lacked a reasonable basis to believe that Teva's and Impax's ANDAs for generic fenofibrate tablets infringed valid and enforceable patents.

98. In bringing and maintaining the Tablet Litigation, Abbott and Fournier also lacked a reasonable basis for alleging that Teva's and Impax's ANDAs for generic fenofibrate tablets infringed the '726 Patent and the Stamm Patents, or any one of them. In addition, Abbott and Fournier never had any objective basis for alleging that Teva's or Impax's Tablet ANDAs or their fenofibrate tablets infringed any of the asserted Stamm Patents because they failed to make a good faith analysis of Impax's and Teva's products and product specifications to determine whether they contained all the elements asserted in each of the Stamm Patents, including the weight limitation. Abbott and Fournier also failed to consider facts and information that Teva and Impax had made known to Abbott and Fournier prior to the filing of the Tablet Litigation. Finally, Abbott and Fournier failed to consider highly relevant and material information Teva and Impax gave them in response to discovery requests during the Tablet Litigation.

99. As previously discussed, Abbott and Fournier sued both Impax and Teva for allegedly infringing the '726 Patent after they sought FDA approval to market fenofibrate capsules (the "Capsule Litigation"). During Abbott's and Fournier's prosecution of the Tablet Lawsuits, Abbott and Fournier knew, as a result of the District Court decision in the Capsule Litigation, that they had no basis for alleging that Teva's fenofibrate tablets infringed the '726 Patent. Clearly, Teva's tablets did not infringe the '726 Patent for the same reasons the court found in the Capsule Litigation that Teva's capsules did not infringe.

100. Moreover, the Federal Circuit's decision in the Capsule Litigation dated March 20, 2003, further confirmed that Abbott and Fournier had no basis for alleging that Teva's fenofibrate tablets infringed the '726 Patent, or for maintaining any action against Teva for infringement of the '726 Patent. Had Abbott and Fournier dismissed their claims against Teva concerning the '726 Patent, as they should have, any automatic stay caused by litigation over the '726 Patent would have been lifted.

101. In addition, the Tablet Lawsuits were baseless in that there was no reasonable basis to believe that the products of Teva and Impax met the other claims limitations of the '670, '726 and '405 Patents as further discussed infra.

102. Teva's and Impax's alleged infringement of the claims of the '670, '405 and '552 Patents rested, in part, on Abbott's and Fournier's proffered interpretation of the patent term "hydrophilic polymer." Abbott's and Fournier's asserted interpretation was directly inconsistent with, and contrary to, the definition of "hydrophilic polymer" explicitly recited in the Stamm Patents themselves. No reasonable litigant objectively and subjectively could have expected to prevail on the claim interpretation of the term

"hydrophilic polymer" that Abbott and Fournier asserted in the Original Tablet and the '552 Lawsuits. In the Original Tablet and the '552 Lawsuits, the Court rejected Abbott's and Fournier's proffered interpretation of the term "hydrophilic polymer" and noted that "the specification [in the Stamm Patents] clearly defines the term" in a manner inconsistent with Abbott's and Fournier's proffered interpretation.

103. The court granted summary judgment of non-infringement of the '670 Patent, claim 9 of the '405 Patent, and the '552 Patent in Teva's and Impax's favor based on the proper interpretation of "hydrophilic polymer."

104. The Tablet Lawsuits, both individually and as a pattern and as part of their overall anti-generic scheme, were brought by Abbott and Fournier intentionally and solely for the purpose of delay and to preclude generic competition. They knew that simply filing the lawsuits, without regard to the merits, would automatically provide a series of 30-month stays to delay FDA approval of Teva's and Impax's ANDAs and would otherwise burden and delay lawful generic competition from Impax, Teva and others. Moreover, they knew they needed to delay generic approval so they could reformulate TriCor, as TriCor 145mg tablets, obtain FDA approval, launch and force the market to convert to TriCor 145mg tablets before generic entry.

105. Abbott and Fournier brought all of the Tablet Lawsuits with the intent to delay and thwart generic competition without regard to the merits of these actions. Many of Abbott's and Fournier's infringement claims in the Tablet Lawsuits were the subject of successful summary judgment motions brought by Teva and Impax. After Abbott and Fournier converted the market, they dismissed all claims and Tablet Lawsuits that had not already been dismissed or terminated. These dismissals further reflect Abbott's and

Fournier's true purpose in bringing and maintaining the Tablet Lawsuits, to delay generic competition. The filing and maintenance of the Tablet Lawsuits singly and collectively are wrongful and actionable both standing alone and as a component in their overall anti-generic scheme.

D. Abbott and Fournier Forced the Market to Convert a Second Time

1. The Reformulation: Abbott and Fournier Reformulated TriCor to Avoid Competition from an AB-Rated Drug and to Justify their Marketing Campaign

106. During 2002, Abbott and Fournier met and planned to reformulate TriCor for a second time, this time by reducing the dosage from 160mg and 54mg to 145mg and 48mg tablets ("TriCor 145mg Tablets") and by seeking to change the dosing instructions on the basis that the reformulated tablets had "no food effect" ("NFE"), meaning they would perform similarly whether taken with or without a meal.

107. In the fall of 2003, Abbott filed with the FDA the NDA for TriCor 145mg Tablets. To support this NDA, Abbott demonstrated the reformulated TriCor 145mg Tablets were bioequivalent to the TriCor 200mg Capsules. In other words, Abbott demonstrated that the TriCor 145mg Tablets performed with substantially the same efficacy as the TriCor 200mg Capsules, and it relied upon the same clinical efficacy and safety data that Fournier had submitted to the FDA in 1998 when it sought approval for the TriCor 200mg Capsules. This showing of bioequivalency meant that the TriCor 145mg Tablets were as safe and as effective as the TriCor 200mg Capsules, and vice versa.

108. The reformulated TriCor 145mg Tablets contained just 15 milligrams less fenofibrate than the TriCor 160mg Tablets. Because the reformulated tablet was, like

TriCor 160mg Tablets, still bioequivalent to the original 200mg TriCor Capsules, the dosage change was clinically meaningless. Abbott and Fournier expected most physicians, health care plans, and third-party payors to view this distinction as insignificant. Reflecting that Abbott and Fournier anticipated that TriCor 145mg Tablets would be viewed the same as TriCor 160mg Tablets, they priced TriCor 145mg Tablets the same as TriCor 160mg Tablets. The real significance of the lower dose was that it prevented TriCor 145mg Tablets from being given an AB rating to TriCor 160mg Tablets.

109. Abbott also claimed that TriCor 145mg Tablets had NFE, meaning the reformulated tablets would be absorbed at the same rate regardless of whether they were consumed with a meal. This modified dosing instruction provided Abbott with a way to differentiate TriCor 145mg Tablets from TriCor 160mg Tablets in their marketing materials. Abbott lacked any evidence that patients would benefit from this change.

2. The Switch: Abbott Launched a Marketing Blitz

110. In March 2004, both Teva and Impax received preliminary approval from the FDA for their ANDAs for a generic fenofibrate tablet. With FDA approval of generic entry delayed by patent-based litigation stays, Abbott and Fournier made plans for an aggressive launch of the TriCor 145mg Tablets.

111. Abbott and Fournier knew that an effective and complete conversion of TriCor 160mg Tablets to TriCor 145mg Tablets would protect TriCor from any AB-rated generic. Whereas the first switch had been virtually completed in six months, Abbott and Fournier hoped to execute a switch to the 145mg Tablet in half that time. They estimated that if they accomplished the switch and conversion to TriCor 145mg Tablets before a

generic version of TriCor 160mg Tablets could enter the market, they would earn hundreds of millions of dollars more in revenues.

112. On November 5, 2004, Abbott received FDA approval of the TriCor 145mg Tablets and, with Fournier, immediately launched an expensive marketing campaign, which sent an expanded Abbott and Fournier sales force canvassing physicians across the country to "educate" them on the reformulated TriCor and to persuade them to switch their prescriptions to the new formulation. Abbott and Fournier sales representatives also contacted pharmacists and managed health care organizations across the country to encourage them to stock TriCor 145mg Tablets and to include the reformulated products in their formularies of covered drugs. In this marketing blitz, Abbott's and Fournier's sales representatives touted the reformulated product, especially the NFE claim.

113. However, Abbott and Fournier knew that many members of the health care community would view their reformulated product with skepticism. Their own marketing studies showed that whether TriCor could be taken without a meal was not viewed as a significant issue among most physicians.

3. The Forced Conversion: Abbott and Fournier Discontinued Sales and Production of TriCor 160mg Tablets

114. To further ensure conversion of the market to TriCor 145mg Tablets, Abbott and Fournier stopped making and selling the TriCor 160mg Tablets. During the fall of 2004, in anticipation of FDA approval of the reformulated TriCor 145mg Tablets, they slowed production of TriCor 160mg Tablets and carefully bled-down inventories of

TriCor 160mg Tablets. In early November 2004, when they launched TriCor 145mg Tablets, they completely stopped production and sales of TriCor 160mg Tablets.

115. Because of this inventory reduction, Abbott ran the risk of running out of TriCor stock if the new formulation was not approved by September 2004. Abbott's and Fournier's slow-down in production facilitated the depletion of TriCor 160mg Tablets on the market following the launch of TriCor 145mg Tablets, thereby helping to force the medical community to adopt the reformulated product. These efforts also helped to ensure that TriCor 160mg Tablets would not be commercially available within the distribution chain by the time a generic entered the fenofibrate market.

4. The Purge: Abbott Reclaimed TriCor 160mg Tablets

116. Initially, Abbott and Fournier hoped to remove TriCor 160mg Tablets from the market by simply bleeding down the existing retail inventories within the distribution chain, i.e., the inventories of wholesalers and retail pharmacies. However, as they awaited FDA approval of TriCor 145mg Tablets, their concern about impending generic entry increased and they sought to accelerate that removal. Abbott and Fournier made plans and budgeted for other means of removing TriCor 160mg Tablets from the market.

117. In March 2005, several months after introducing TriCor 145mg Tablets, Abbott wrote to retail chains and wholesalers requesting that they return any remaining TriCor 160mg Tablets in exchange for discounts and credits.

118. In offering this incentive to wholesalers and retail pharmacies, Abbott deviated from its standard policy for returned goods. Abbott's policy was to provide an allowance on returned goods equal to 1% of total sales. Instead, to encourage the return

of TriCor 160mg Tablets, Abbott crafted a special tablet-exchange program and buy-back policy for TriCor 160mg Tablets.

119. This additional tactic prompted the return of TriCor 160mg Tablets worth over $6.0 million dollars. Following Abbott's recovery of TriCor 160mg Tablets, the tablets were destroyed.

120. Abbott's efforts to reclaim the remaining TriCor 160mg Tablets from the market prior to generic entry succeeded in ensuring that all or nearly all pharmacists did not have any TriCor 160mg Tablets on their shelves by the time the generic version of the product was able to enter the market. These efforts further helped to ensure that TriCor 160mg Tablets would not be commercially available within the distribution chain by the time a generic entered the fenofibrate market.

121. Abbott's and Fournier's forced conversion strategy was successful, and by February of 2005 most prescriptions for TriCor were for TriCor 145mg Tablets. By May 2005, Abbott had depleted its inventory of TriCor 160mg Tablets and had killed TriCor 160mg Tablets.

5. The Final Nail: Abbott and Fournier Interfered With the Normal and Customary Methods Generics Use to Compete

122. As they had done following the first switch from TriCor 200mg Capsules to TriCor 160mg Tablets, Abbott and Fournier effectively removed the TriCor 160mg Tablets from First DataBank's NDDF, a pharmaceutical industry resource relied upon by many physicians, pharmacists and third-party payors, thus removing any meaningful reference to this product.

123. In May of 2005, Abbott notified First DataBank that they had discontinued TriCor 160mg Tablets and thereby "obsoleted" TriCor 160mg Tablets. Thereafter, the reference was removed from the NDDF.

124. Once the reference to TriCor 160mg Tablets was removed from the NDDF, the subsequently approved generic 160mg tablets were coded as a "single-source" product. As a result, many healthcare insurers treated the generic product as a brand name drug and did not give it preferred status on their formularies, causing higher co-pays for consumers.

125. By designating the TriCor 160mg Tablets as "obsolete" in the NDDF, Abbott and Fournier prompted the removal of information from the market that would have informed physicians and pharmacists that Teva's generic drug was AB-rated to the TriCor 160mg Tablets, making it more difficult for a generic competitor to enter or compete in the fenofibrate market.

E. Abbott and Fournier Thwarted Generic Entry

126. Following Abbott's direction to First DataBank to "obsolete" TriCor 160mg Tablets, the trial court in the Tablet Litigation entered a partial summary judgment in Teva's favor, which lifted the 30-month stay against FDA approval of the Teva ANDA, and the FDA granted final approval to Teva's generic version of the TriCor 160mg Tablets.

127. Teva was then legally able to enter the fenofibrate market with a generic version of the TriCor 160mg Tablets. But Abbott's and Fournier's withdrawal of TriCor 160mg Tablets and conversion of the fenofibrate market was complete. Abbott and

Fournier had, again, foreclosed competition against TriCor and had denied consumers the choice of a generic fenofibrate tablet.

Anticompetitive Effects

128. Abbott's and Fournier's acts, practices, and scheme discussed herein were for the purpose of, and had the effect of, restraining competition unreasonably by preventing the entry of generic fenofibrate drugs.

129. Absent Abbott's and Fournier's illegal anticompetitive conduct, at least one generic competitor would have begun marketing a generic version of fenofibrate.

130. If a generic competitor had been able to enter the relevant market at either the time of the capsule or tablet switch and thereby compete with Abbott and Fournier, consumers and state entities (payors and reimburses) would have had the choice to substitute, and many would have substituted a lower-priced generic for the higher-priced brand-name drug.

131. By preventing generic competitors from entering the market, Abbott and Fournier have deprived Plaintiff States and their consumers of the benefits of the competition that the federal and state antitrust laws, consumer protection laws and/or unfair competition statutes and related state laws are designed to promote, preserve, and protect.

Injury

132. As a direct and proximate result of the unlawful conduct alleged above, Plaintiff States and consumers were not and are not able to purchase, or pay reimbursements for purchases of, fenofibrate at prices determined by free and open

competition. Instead, they were forced to pay artificially high monopoly prices. Consequently, they have been injured in their business and property in that, *inter alia*, they have paid more and continue to pay more for fenofibrate than they would have paid in a free and open competitive market. The Plaintiff States cannot quantify at this time the precise amount of monetary harm which they have sustained, but allege that such harm is substantial.

133. As a direct and proximate result of the unlawful conduct alleged above, the general economies of the Plaintiff States have sustained injury and the Plaintiff States are threatened with continuing injury to their business and property unless Abbott and Fournier are enjoined from their unlawful conduct.

134. As a direct and proximate result of the unlawful conduct alleged above, Abbott and Fournier have unjustly profited through inflated profit margins and will continue to do so.

135. Abbott's and Fournier's unlawful conduct is continuing and will continue unless the injunctive and equitable relief requested by the Plaintiff States is granted.

136. Plaintiff States do not have an adequate remedy at law.

Count I: Monopolization under Sherman Act §2

137. The preceding paragraphs are incorporated as if set forth herein.

138. From 1998 to the present, Abbott has possessed monopoly power in the relevant market of fenofibrate products in the United States.

139. Abbott willfully and unlawfully maintained its monopoly power by engaging in exclusionary conduct which had the intent, purpose and effect of illegally

preventing and blocking competition in the United States fenofibrate market in violation of Section 2 of the Sherman Act, 15 U.S.C. §2.

140. Beginning in 1998, Abbott engaged in exclusionary conduct including, but not limited to: devising and implementing an anti-generic strategy, wrongfully asserting that Teva's and Impax's 200mg fenofibrate ANDAs infringed the '726 Patent, improperly procuring and enforcing the Stamm Patents, wrongfully listing the Stamm Patents in the Orange Book, systematically asserting unenforceable patents against Teva's and Impax's non-infringing 160mg fenofibrate ANDAs, stopping sales of 200mg Capsules and 160mg Tablets to force the market to accept the reformulated TriCor tablets that provided no new clinical benefit to patients, soliciting and accepting returns of TriCor 200mg Capsules and 160mg Tablets to accelerate the forced conversion scheme, and obsoleting any references, including the NDC number, from the NDDF for TriCor 200mg Capsules and TriCor 160mg Tablets.

141. As a direct and proximate result of Abbott's exclusionary scheme, generic manufacturers have been unable to market and sell generic alternatives that pharmacists can substitute for TriCor prescriptions. Plaintiff States and consumers, therefore, have been injured in their business or property because they had to purchase TriCor without the reasonable availability of a lower-priced generic alternative.

Count II: Conspiracy to Monopolize under Sherman Act §2

142. The preceding paragraphs are incorporated as if set forth herein.

143. Abbott and Fournier conspired to monopolize and did unlawfully monopolize the relevant market for fenofibrate products in the United States, thereby violating Section 2 of the Sherman Act, 15 U.S.C. §2.

144. Abbott and Fournier have acted in concert to maintain willfully and unlawfully their monopoly power in the relevant market for fenofibrate drugs in the United States by engaging in unlawful exclusionary conduct which had the purpose and effect of unreasonably restraining competition.

145. Abbott and Fournier engaged in their conspiracy with the specific intent to prevent generic competition in the United States fenofibrate market.

146. Abbott and Fournier committed a series of acts in furtherance of their conspiracy, including, but not limited to: devising and implementing an anti-generic strategy that involved wrongfully asserting that Teva's and Impax's 200mg fenofibrate ANDAs infringed the '726 Patent, improperly procuring and enforcing the Stamm Patents, wrongfully listing the Stamm Patents in the Orange Book, systematically enforcing unenforceable patents against Teva's and Impax's, non-infringing 160mg fenofibrate ANDAs, stopping sales of 200mg Capsules and 160mg Tablets to force the market to accept reformulated TriCor products that provided no new clinical benefit to patients, soliciting and accepting returns of TriCor 200mg Capsules and 160mg Tablets to accelerate the forced conversion scheme, and obsoleting any reference, including the NDC number, from the NDDF for TriCor 200mg Capsules and TriCor 160mg Tablets.

147. The conspiracy between Abbott and Fournier created a realistic threat to competition in the United States fenofibrate market.

148. As a direct and proximate result of Abbott's and Fournier's exclusionary scheme, generic manufacturers have been unable to market and sell generic alternatives that pharmacists can substitute for TriCor prescriptions. Plaintiff States and consumers,

therefore, have been injured in their business or property because they had to purchase TriCor without the reasonable availability of a lower-priced generic alternative.

Count III: Illegal Restraint of Trade under Sherman Act §1

149. The preceding paragraphs are incorporated as if set forth herein.

150. From 1998 to the present, Abbott and Fournier entered into a contract, combination, or conspiracy to restrain trade in the U.S. market for fenofibrate drugs and thereby violated Section 1 of the Sherman Act, 15 U.S.C. §1.

151. From 1998 to the present, Abbott and Fournier have possessed market power in the relevant market. Abbott and Fournier have willfully and unlawfully maintained their market power by excluding generic competitors from the relevant market.

152. From 1998 to present, Abbott and Fournier unreasonably restrained trade through an exclusionary scheme that included, among other things: planning and committing a series of acts in furtherance of their conspiracy, devising and implementing an anti-generic strategy that involved wrongfully asserting that Teva's and Impax's 200mg fenofibrate ANDAs infringed the '726 Patent, improperly procuring and enforcing the Stamm Patents, wrongfully listing the Stamm Patents in the Orange Book, systematically asserting unenforceable patents against Teva's and Impax's non-infringing 160mg fenofibrate ANDAs, stopping sales of 200mg Capsules and 160mg Tablets to force the market to accept reformulated TriCor products that provided no new clinical benefit to patients, soliciting and accepting returns of TriCor 200mg Capsules and 160mg Tablets to accelerate the forced conversion scheme, and obsoleting any reference,

including the NDC number, from the NDDF for TriCor 200mg Capsules and TriCor 160mg Tablets.

153. As a direct and proximate result of Abbott's and Fournier's exclusionary scheme, generic manufacturers have been unable to market and sell generic alternatives that pharmacists can substitute for TriCor prescriptions. Plaintiff States and consumers, therefore, have been injured in their business or property because they had to purchase TriCor without the reasonable availability of a lower-priced generic alternative.

154. The anticompetitive effects of Abbott's and Fournier's conspiracy outweigh pro-competitive effects, if any, that their conduct may have had.

Count IV: State Law Claims

Arizona

155. Plaintiff State of Arizona repeats and realleges each and every allegation contained in paragraphs 1 through 154.

156. Defendants' acts violates the Arizona Uniform State Antitrust Act, A.R.S. §§44-1401, *et seq.*, and Plaintiff State of Arizona, on behalf of itself, its states agencies and all persons who directly or indirectly purchased TriCor or fenofibrate-containing products, is entitled to relief thereunder.

Arkansas

157. Plaintiff State of Arkansas repeats and realleges each and every allegation contained in paragraphs 1 through 154.

158. Defendants' acts violate, and Plaintiff State of Arkansas is entitled to relief on behalf of consumers and state government entities under the Arkansas Deceptive

Trade Practices Act, Ark. Code Arm. §4-88-101, *et seq.*, and the Arkansas Unfair Practices Act, Ark. Code Ann. §4-75-301, *et seq.*

California

159. Plaintiff State of California realleges and incorporates all of the allegations above from paragraphs 1 through 154.

160. The aforementioned practices by Defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. code sections 16700, *et seq.*, and the California Unfair Competition Act, Cal. Bus. & Prof. Code, sections 17200, *et seq.* As a result of Abbott's and Fournier's anticompetitive acts and unfair and deceptive practices and violations of the California's Cartwright Act and Unfair Competition Act, all as more fully described above, the State of California and its residents have suffered and been injured in business and property and will continue to suffer ascertainable loss and damages in an amount to be determined at trial.

161. Accordingly, the State of California, including its state agencies, on behalf of itself and its residents, seeks all relief available under California's Cartwright Act and the Unfair Competition Act, including damages, restitution, disgorgement, unjust enrichment, injunctions, treble damages, costs, reasonable attorneys' fees, and/or civil penalties, and any such other equitable or monetary relief that might be available under statute or equity.

Connecticut

162. Plaintiff State of Connecticut repeats and realleges each and every allegation contained in paragraphs 1 through 154.

163. Defendants' acts violate, and Plaintiff State of Connecticut is entitled to relief under, the Connecticut Antitrust Act, Conn. Gen. Stat. §35-24, *et seq.*, and the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. §42-110a, *et seq.*

District of Columbia

164. The District of Columbia realleges and incorporates all of the allegations above from paragraphs 1 through 154.

165. Defendants' acts violated provisions of the District of Columbia Antitrust Act, D.C. Code §28-4502 (2001) and D.C. Code §28-4503 (2001). These acts restrained competition in Defendants' sale of TriCor or fenofibrate-containing products in the District of Columbia.

166. The District of Columbia (District), its political subdivisions and public agencies, along with residents of the District, have been injured by Defendants' actions, by reason of paying artificially inflated prices as direct or indirect purchasers of TriCor or fenofibrate-containing products.

167. Plaintiff, the District, for its political subdivisions and public agencies, and as parens patriae on behalf of persons residing in the District, is entitled to monetary relief for injuries directly or indirectly suffered by the District, its political subdivisions and public agencies, and said persons, by reasons of the violations alleged above.

Florida

168. Plaintiff State of Florida realleges and incorporates all of the allegations above from paragraphs 1 through 154.

169. The State of Florida, its departments, agencies and units of government purchased TriCor from Abbott through contracts that are assigned to the State of Florida. The State of Florida, Office of the Attorney General, asserts claims for damages and penalties under the Florida Antitrust Act on behalf of such entities, pursuant to § 542.27(2), Florida Statutes.

170. As described above Defendants' acts violate § 542.18, Florida Statutes, and the State of Florida is entitled to relief, including damages, under § 542.22, Florida Statutes, for all direct purchases made pursuant to contracts that are assigned to the State of Florida.

171. The State of Florida is entitled to a civil penalty of up to the maximum amount permitted by § 542.21, Florida Statutes, for each violation of § 542.18, Florida Statutes.

172. The State of Florida is entitled to recover its costs and attorneys' fees pursuant to § 542.22(2), Florida Statutes.

173. The State of Florida requests that the Court order such additional relief as it may deem just and proper.

174. Certain Florida governmental entities and individuals residing in Florida purchased TriCor from Abbott. The State of Florida, Office of the Attorney General, asserts claims for damages under the Florida Deceptive and Unfair Trade Practices Act on behalf of such entities and individuals, pursuant to § 501.207(1)(c), Florida Statutes.

175. As described above, Defendants' unfair methods of competition and unconscionable acts and practices in the conduct of trade and commerce offend established public policy and are immoral, unethical, oppressive, unscrupulous or

substantially injurious to governmental entities and individuals resident in the State of Florida. Thus, Defendants' unfair methods of competition and unconscionable acts and practices in the conduct of trade and commerce violate § 501.204, Florida Statutes.

176. The sale of TriCor involves the conduct of "trade or commerce" within the meaning of § 501.203(8), Florida Statutes.

177. The Attorney General of Florida has reviewed this matter and determined that an enforcement action serves the public interest.

178. The State of Florida is entitled to relief, including damages, under § 501.207, Florida Statutes, for all direct and indirect purchases from Defendants.

179. The State of Florida is entitled to a civil penalty of up to the maximum amount permitted by §§ 501.2075 or 501.2077, Florida Statutes, as applicable, for each violation of § 501.204, Florida Statutes.

180. The State of Florida is entitled to recover its costs and attorneys' fees pursuant to § 501.2105, Florida Statutes.

181. The State of Florida requests that the Court order such additional relief as it may deem just and proper.

Idaho

182. Plaintiff State of Idaho, ex rel. Lawrence G. Wasden, Attorney General of Idaho ("State of Idaho"), realleges and incorporates all of the allegations above from paragraphs 1 though 154.

183. The State of Idaho represents itself, including its state agencies, and, as parens patriae, its persons, as defined by Idaho Code Section 48-103(2) of the Idaho Competition Act, residing in the State of Idaho who have purchased TriCor.

184. Defendants' acts, as set forth above, had the purpose and effect of suppressing competition in the sale of TriCor in Idaho and elsewhere, as well as a substantial and adverse impact on prices for TriCor in the State of Idaho and constitute:

a. an unreasonable restraint of Idaho commerce, as defined by Idaho Code Section 48-103(1) of the Idaho Competition Act, and

b. an unlawful monopolization and conspiracy to monopolize any line of Idaho commerce.

185. Defendants' acts have caused substantial injury and damage to the State of Idaho, its state agencies, and to persons in the State of Idaho.

186. The State of Idaho, on behalf of itself, including its state agencies, and as parens patriae, its persons residing in the State of Idaho who have purchased TriCor, is entitled to relief under the Idaho Competition Act, Idaho Code § 48-101 *et seq*.

187. The Defendants' activities are per se or intentional violations of the Idaho Competition Act, Idaho Code Sections 48-104 and 48-105. Pursuant to Idaho Code Section 48-108(2) of the Idaho Competition Act, the State of Idaho, possess authority, as parens patriae, to seek three times the total damages sustained, directly or indirectly, by persons residing in Idaho.

188. Pursuant to Idaho Code Section 48-108(1)(c) of the Idaho Competition Act, the State of Idaho, including its state agencies, is authorized to recover its actual damages or restitution.

189. Pursuant to Idaho Code Section 48-108(1)(d) of the Idaho Competition Act, the State of Idaho is authorized to seek from Defendants civil penalties of up to

$50,000 per violation of Idaho Code Sections 48-104 and 48-105 of the Idaho Competition Act.

190. Pursuant to Idaho Code Section 48-108(1)(d) of the Idaho Competition Act, the State of Idaho is authorized to seek from Defendants attorney fees, reasonable expenses, and investigative costs.

Iowa

191. Iowa realleges and incorporates all of the allegations above from paragraphs 1 through 154.

192. Defendants' acts as alleged in this complaint violate the Iowa Competition Act, Iowa Code sections 553, *et seq.*, the Iowa Consumer Fraud Act, Iowa Code section 714.16, and Iowa common law, and Plaintiff State of Iowa is entitled to all remedies available for such violations including damages for injuries sustained by state government agencies.

Kansas

193. Plaintiff State of Kansas repeats and realleges each and every allegation contained in paragraphs 1 through 154.

194. Defendants' acts violate, and Plaintiff State of Kansas is entitled to relief under, the Kansas Restraint of Trade Act, Kan. Stat. Ann §50-101, *et seq.* Plaintiff State of Kansas is entitled to all remedies available for violations of these provisions including civil penalties up to the maximum amount permitted by K.S.A. 50-160, treble damages for injuries sustained by state government agencies and purchasers pursuant to K.S.A. 50-161(b), and reasonable attorneys' fees and costs pursuant to K.S.A. 50-161(c).

Maine

195. Plaintiff State of Maine realleges and incorporates all of the allegations above from paragraphs 1 through 154.

196. Defendants' acts violate the Maine Monopolies and Profiteering Law, 10 MRSA §§1101 and 1102, and Plaintiff State of Maine is entitled under 10 MRSA §1104 to the following relief:

a. Treble damages for injuries suffered directly or indirectly on behalf of itself, its state agencies and its citizens as parens patriae; (b) injunctive relief to restrain continuing violations of law; (c) civil penalties in the amount of $100,000 for each course of conduct alleged herein that constitutes a violation of 10 M.R.S.A §§1101 or 1102; and (d) necessary and reasonable costs, expert fees and attorney fees.

Maryland

197. Plaintiff State of Maryland realleges and incorporates all of the allegations above from paragraphs 1 through 154.

198. The aforementioned practices by Defendants were, and are in violation of the Maryland Antitrust Act, Md. Com. Law Code Ann. §§11-201 through 213.

199. During the relevant period, TriCor and other fenofibrate products were in the regular, continuous and substantial flow of intrastate commerce in Maryland. TriCor was shipped to pharmacies located in Maryland which sold TriCor to persons in Maryland. TriCor purchases were also paid for by the Maryland Pharmacy Program (which serves Maryland Medicaid clients) and by Maryland's prescription benefits program (which serves Maryland employees and retirees).

200. During the relevant period, the Maryland Pharmacy Program paid in excess of $3.2 million for TriCor. Maryland's State Employee and Retiree Health and Welfare Benefits Program paid in excess of $8.6 million for TriCor. As a result of the defendants' unlawful conduct, consumers, the Maryland Pharmacy Program and the State Employee and Retiree Health and Welfare Benefits Program paid more for TriCor than they would have paid in a competitive market.

201. Plaintiff State of Maryland brings this action against Defendants in the following capacities:

a. Pursuant to Md. Com. Law Code Ann. §11-209(a) in its sovereign capacity for injunctive relief, civil penalties and all other available equitable remedies; (b) pursuant to Md. Com. Law Code Ann. §11-209(b) to recover three times the amount of damages sustained by the Maryland Pharmacy Program and Maryland's prescription benefits program. These Maryland State entities are entitled to money damages regardless of whether they purchased TriCor directly or indirectly from Defendants. Md. Com. Law Code Ann. §11-209(b)(2); (c) pursuant to Md. Com. Law Code Ann. §11-209(b)(5) as parens patriae on behalf of persons residing in Maryland. These persons are entitled to three times the amount of money damages sustained regardless of whether they purchased TriCor directly or indirectly from Defendants. Md. Health-Gen. Code Ann. §21-1114.

202. Plaintiff State of Maryland also seeks, pursuant to Md. Com. Law Code §11-209(b) reimbursement of reasonable attorneys fees, expert fees and costs.

Massachusetts

203. The Commonwealth of Massachusetts incorporates paragraphs 1 through 154 as if fully restated here.

204. By virtue of the foregoing, defendants have engaged in unfair methods of competition and unfair or deceptive acts or practices in violation of the Massachusetts Consumer Protection Act, G.L. c. 93A, § 2.

205. Defendants knew or should have known that their conduct violated the Commonwealth of Massachusetts' Consumer Protection Act, MGL. c. 93A, § 2.

Michigan

206. Plaintiff State of Michigan repeats and realleges each and every allegation contained in paragraphs 1 through 154.

207. The Michigan Attorney General proceeds on behalf of the Plaintiff State of Michigan, its state agencies and as parens patriea on behalf of all consumers under Mich. Comp. Laws Ann. § 14.28 and § 14.101, Mich Comp. Laws Ann. § 455.778, and the common law of Michigan.

208. The aforementioned practices by Defendants were and are in violation of the Michigan Consumer Protection Act, Mich Comp. Laws Ann. § 445.901 *et seq.*, and the Michigan Antitrust Reform Act, Mich. Comp. Laws Ann. § 445.771, *et seq.*

209. As a result of Defendants' unfair, unconscionable, or deceptive methods, acts or practices in the conduct of trade in violation of the Michigan Consumer Protection Act and Defendants' conspiracy to monopolize and actual monopolization of the fenofibrate market for the purpose of excluding competition in violation of the Michigan Antitrust Reform Act, all as more fully described above, the Plaintiff State of Michigan

and its consumers have suffered and been injured in business and property by reason of paying artificially inflated prices as direct or indirect purchasers of TriCor and will continue to suffer ascertainable loss and damages in an amount to be determined at trial.

210. Accordingly, Plaintiff State of Michigan, on behalf of itself, its agencies, and as parens patriae on behalf of its consumers that directly or indirectly purchased TriCor, is entitled to injunctive relief, civil penalties, damages, costs and attorney's fees under the Michigan Consumer Protection Act, Mich Comp Law Ann. § 445.901 *et seq.*, the Michigan Antitrust Reform Act, Mich. Comp. Laws Ann. § 445.771, *et seq.*, and the common law of Michigan, and requests that the Court order such additional relief as it may deem just and proper.

Minnesota

211. Plaintiff State of Minnesota repeats and realleges each and every allegation contained in paragraphs 1 through 154.

212. Defendants' acts violate, and Plaintiff State of Minnesota on behalf of itself, its state agencies, and as parens patriae on behalf of its consumers is entitled to relief under the Minnesota Antitrust Law of 1971, Minn. Stat. §§ 325D.49-.66, the Uniform Deceptive Trade Practices Act of 1973, Minn. Stat. §§ 325D.43-.48, Minn. Stat. Chapter 8, and Minnesota common law for unjust enrichment.

213. Plaintiff State of Minnesota is entitled to treble damages under Minn. Stat. § 325D.57. Plaintiff State of Minnesota is entitled to costs and reasonable attorneys' fees under Minn. Stat. § 325D.45 and .57. Plaintiff State of Minnesota is entitled to injunctive relief under Minn. Stat. §§ 325D.45 and .58.

214. Defendants shall be subject to civil penalties under Minn. Stat. § 325D.56.

Missouri

215. Plaintiff State of Missouri repeats and realleges each and every allegation contained in paragraphs 1 through 154 with the same force and effect as if here set forth in full.

216. The aforementioned acts and practices of the Defendants were in violation of the Missouri Antitrust Law, specifically, §416.031 Revised Statutes of Missouri (RSMo) 2000. The State of Missouri brings this action both on behalf of itself and its public agencies, including by right of assignment, and as parens patriae as to natural persons, to enforce public rights and to protect citizen consumers against the violation of such laws and, specifically, seeks injunctive relief, damages and all other relief available pursuant to §416.071 and §416.121, RSMo (2000).

217. The aforementioned acts and practices of the Defendants were also in violation of the Missouri Merchandising Practices Act, §407.020, RSMo 2000, and the Missouri Code of State Regulations, specifically 15 CSR 60-7.010 *et seq.*, 15 CSR 60-8.010, *et seq.*, and 15 CSR 60-9.010, *et seq.*, which prohibit the act, use or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact in connection with the sale or advertisement of any merchandise in trade or commerce, including such acts, uses and employments, committed before, during or after the sale. The Attorney General brings this action in its sovereign capacity to enforce such law and to obtain the relief available pursuant to §§ 407.100, 407.130 and 407.140, RSMo (2000), including injunctions, restitution, the assessment of civil penalties and recovery of all costs of its investigation and litigation as provided therein.

Nevada

218. Plaintiff State of Nevada repeats and realleges each and every allegation contained in paragraphs 1 through 154.

219. The State of Nevada represents itself, its state agencies, and its natural persons who have purchased TriCor. Defendants' acts violate the Nevada Unfair Trade Practice Act, Nev. Rev. Stat. § 598A, *et seq.*, including Nev. Rev. Stat. § 598A.060. Plaintiff is entitled to recover actual damages, treble damages, and reasonable attorneys' fees and costs under Nev. Rev. Stat. § 598A.160 and Nev. Rev. Stat. § 598A.200, injunctive relief under Nev. Rev. Stat. § 598A.070, and civil penalties in an amount not to exceed 5 percent of the gross income realized by the sale of TriCor by the Defendants in the State of Nevada in each year in which the prohibited activities occurred pursuant to Nev. Rev. Stat. § 598A.170.

New York

220. Plaintiff State of New York repeats and realleges each and every allegation contained in paragraphs 1 through 154.

221. The State of New York brings this action in its sovereign capacity to protect its citizens and recover civil penalties.

222. The State of New York brings this action on behalf of itself and its public state and local entities that purchased TriCor directly and/ or indirectly.

223. The State of New York brings this action as parens patriae as to natural persons who purchased TriCor directly and/or indirectly.

224. Defendants' acts unreasonably restrained trade and commerce causing injury and damage to public state and local entities and natural persons in the State in

violation of New York General Business Law §§340 - 347, and Plaintiff New York is entitled to damages, injunctive relief, penalties and other appropriate relief thereunder.

225. Defendants engaged in repeated and persistent fraudulent and illegal acts in the conduct of their business to thwart competition from generic fenofibrate in violation of New York Executive Law §63(12), and Plaintiff New York is entitled to damages, injunctive relief, penalties and other appropriate relief thereunder.

226. By unlawfully thwarting competition from generic fenofibrate, Defendants wrongfully deprived purchasers of the lower, competitive price that generic fenofibrate would have sold for in a free and open competitive market. Defendants thereby wrongfully appropriated for themselves monetary benefits that they would not have had in a competitive market, and have been unjustly enriched. Plaintiff New York is entitled to restitution, disgorgement and other appropriate relief as a result of Defendants' unlawful conduct.

North Carolina

227. Plaintiff State of North Carolina repeats and realleges each and every allegation contained in paragraphs 1 through 154.

228. Defendants' acts violate North Carolina's Unfair and Deceptive Trade Practices Act, N.C. Gen. Stat. § 75-1 *et seq.* Plaintiff State of North Carolina, on behalf of itself, its state agencies and all persons who directly or indirectly purchased TriCor or fenofibrate-containing products, is entitled to relief under N.C. Gen. Stat. §§ 75-1, 75-1.1, 75-2 and 75-2.1 and the common law of North Carolina.

229. Plaintiff State of North Carolina is entitled to a civil penalty under N.C. Gen. Stat. §§ 75-8 and 75-15.2 of up to $5,000.00 for each violation, or each week of

defendants' continuing violation, as defendants' acts were knowingly violative of North Carolina law.

230. Plaintiff State of North Carolina is entitled to recover its costs and attorneys' fees pursuant to N.C. Gen. Stat. § 75-16.1 because defendants have willfully engaged in acts that violate North Carolina law and there has been an unwarranted refusal by defendants to fully resolve the matter which constitutes the basis of such suit.

Ohio

231. Plaintiff State of Ohio realleges and incorporates all of the allegations from paragraph 1 through 154.

232. The aforementioned practices by Abbott and Fournier were in violation of Ohio's Antitrust law, the Ohio Valentine Act, Ohio Rev. Code §§1331.01 *et seq.* and the common law of Ohio.

233. Pursuant to Ohio Rev Code §§1331.01 *et seq.*, §109.81, §109.82 and the common law of Ohio, Plaintiff State of Ohio is entitled injunctive relief, civil penalties and the recovery of attorney's fees and costs.

Oregon

234. Plaintiff State of Oregon, ex rel. Hardy Myers, Attorney General of Oregon ("State of Oregon" or "Oregon"), realleges and incorporates all of the allegations above from paragraphs 1 through 154.

235. The State of Oregon represents itself, including its state agencies, and as parens patriae, its political subdivisions and natural persons in the State who have purchased TriCor.

236. Defendants' acts of conspiracy and unreasonable restraint of trade and commerce had the purpose and effect of suppressing competition in the sale of TriCor in Oregon and elsewhere, and had a substantial and adverse impact on prices for TriCor in Oregon.

237. Defendants' acts have caused substantial injury and damage to the State of Oregon, its state agencies and political subdivisions, and to natural persons in the State.

238. The State of Oregon, on behalf of itself, including its state agencies, and as parens patriae, its political subdivisions and natural persons in the State who purchased TriCor, is entitled to relief under the Oregon Antitrust Law, Oregon Revised Statutes § ("ORS") 646.705, *et seq.*

239. The Defendants' activities are *per se* violations of Oregon's Antitrust Law, ORS 646.725 and ORS 646.730. Pursuant to ORS 646.760, 646.770, ORS 646.775, and ORS 646.780, the Attorney General of Oregon possesses authority to seek equitable and monetary relief for antitrust injuries sustained by the State, including its state agencies, and by its political subdivisions and natural persons in the State.

240. Pursuant to ORS 646.775 and ORS 646.780, the State of Oregon is entitled to recover three times the total damages sustained by the State, including its state agencies, and by its political subdivisions and natural persons in the State, by reason of Defendants' violations of the Oregon Antitrust Law.

241. Pursuant to ORS 646.760, Defendants are each liable to the State of Oregon for civil penalties of $250,000 for each of their violations of the Oregon Antitrust Law.

242. Pursuant to ORS 646.760, 646.770, ORS 646.775, and ORS 646.780, the State of Oregon is entitled to its costs incurred in bringing this action, plus reasonable attorney fees, expert witness fees and costs of investigation.

Pennsylvania

243. The Commonwealth of Pennsylvania realleges and incorporates all of the allegations above from paragraphs 1 through 154.

244. The acts and practices of Defendants, as set forth herein, constitute unfair methods of competition and unfair or deceptive acts or practices in the conduct of Defendants' business in violation of the Unfair Trade Practices and Consumer Protection Law ("UTPCPL").

245. In distributing, marketing and selling TriCor to the Commonwealth and Pennsylvania Consumers, and in otherwise engaging in the conduct more fully described herein with respect to TriCor, Abbott and Fournier, individually and jointly, are engaging in trade or commerce that directly or indirectly harmed consumers in this Commonwealth within the meaning of 73 P.S. §201-2(3).

246. Abbott and Fournier violated the UTPCPL:

a. each time Abbott and/or Fournier prosecuted and obtained multiple patents through inequitable conduct; (b) each time Abbott and/or Fournier listed inequitably obtained patents in the Orange Book as maintained by the Food and Drug Administration; (c) each time Abbott and/or Fournier filed sham patent litigation for the purpose of foreclosing and delaying competition in the market for fenofibrate; (d) each time Abbott and/or Fournier reformulated TriCor to prevent generic entry; (e) each time Abbott and/or Fournier contacted a

prescribing physician to convert the market over to a new formulation of TriCor; (f) each time Abbott and/or Fournier contacted pharmacies to remove prior formulations of TriCor to make it commercially unavailable to prevent generic entry; (g) each time Abbott and/or Fournier interfered with the normal and customary channels of distribution used by generics; (h) each time a medical provider prescribed TriCor; (i) each time a request for reimbursement was made to a Commonwealth of Pennsylvania program for TriCor; (j) each time a patient and/or his or her insurer was charged for TriCor; and (k) each time Abbott and/or Fournier engaged in conduct actionable under the other counts of this Complaint brought by the Commonwealth of Pennsylvania and/or engaged in conduct in violation of the statute and laws of the Commonwealth of Pennsylvania.

247. Abbott's and Fournier's TriCor products reimbursed or purchased by the Commonwealth of Pennsylvania or purchased by Pennsylvania Consumers were used for personal, family or household use.

248. Abbott's and Fournier's conduct, as more fully described herein, constitutes unfair methods of competition and unfair or deceptive acts or practices within the meaning of 73 P.S. §201-2(4), including, but not limited to, the following:

a. causing likelihood of confusion or misunderstanding as to the source, sponsorship, approval or certification of goods or services, within the meaning of 73 P.S. §201-2(4) (ii); (b) representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation or connection that he does not have; within the meaning of 73 P.S. §201-2(4) (v); (c)

engaging in any other fraudulent or deceptive conduct which creates the likelihood of confusion or of misunderstanding; within the meaning of 73 P.S. §201-2(4) (xxi).

249. The Commonwealth of Pennsylvania is empowered to bring this action on behalf of "persons" who have purchased TriCor at artificially-inflated prices and as a result, have suffered, are suffering and will continue to suffer irreparable harm as a result of Abbott's and Fournier's actions. "Persons" include, but are not limited to, natural persons, corporations, trusts, partnerships, incorporated or unincorporated associations and any other legal entities within the meaning of 73 P.S. §201-2(2).

250. The Commonwealth of Pennsylvania also has standing to bring this claim in that the Commonwealth of Pennsylvania is both an end payor and purchaser/reimburser of TriCor through its Medicaid, PACE and state hospitals programs. The Commonwealth of Pennsylvania performs these functions, not for its own business purposes, but rather in its representative capacity on behalf and for the benefit of its constituents who, in turn, make use of TriCor primarily for personal, family and/or household purposes.

251. Defendants agreed to and did, in fact, act in restraint of trade or commerce in a market that includes Pennsylvania, by affecting, fixing, controlling and/or maintaining, at artificial and non-competitive levels, the prices at which fenofibrate was sold, distributed or obtained in Pennsylvania.

252. Defendants deliberately failed to disclose material facts to the Commonwealth of Pennsylvania and Pennsylvania Consumers concerning Defendants' unlawful activities and artificially-inflated prices for fenofibrate. Defendants owed a

duty to disclose such facts and considering the relative lack of sophistication of the average, non-business consumer, Defendants breached that duty by their silence. Defendants misrepresented to all consumers during the relevant period that Defendants' fenofibrate prices were competitive and fair.

253. Defendants' unlawful conduct had the following effects: (1) fenofibrate price competition was restrained, suppressed and eliminated throughout Pennsylvania; (2) fenofibrate prices were raised, fixed, maintained and stabilized at artificially-high levels throughout Pennsylvania; (3) Commonwealth of Pennsylvania and Pennsylvania Consumers were deprived of free and open competition; and (4) Commonwealth of Pennsylvania and Pennsylvania Consumers paid supracompetitive, artificially inflated prices for fenofibrate.

254. As a direct and proximate result of the Defendants' violations of law, Commonwealth of Pennsylvania and Pennsylvania Consumers have and will continue to suffer an ascertainable loss of money or property as a result of Defendants' use or employment of unconscionable and deceptive commercial practices as set forth above. That loss has been caused by Defendants' willful and deceptive conduct, as described herein.

255. Defendants' deception, including its affirmative misrepresentation and omissions concerning the inequitable patent prosecution, improper FDA Orange Book listing and the price of fenofibrate, likely misled all consumers acting reasonably under the circumstances to believe that they were purchasing fenofibrate at prices borne by a free and fair market. Defendants' affirmative misrepresentations and omissions constitute information important to Commonwealth of Pennsylvania and Pennsylvania

Consumers as they related to the choice, efficacy and/or cost of fenofibrate they purchased. Defendants violated the UTPCPL under its "catch-all provision," 73 P.S. §201-2(4) (xxi), by engaging in deceptive conduct which created a likelihood of confusion or misunderstanding as alleged therein and Commonwealth of Pennsylvania seeks all relief available hereunder.

256. Abbott's and Fournier's conduct, individually and jointly, more fully described herein is, accordingly, proscribed and unlawful pursuant to 73 P. S. §201-3.

257. Abbott's and Fournier's conduct, individually and jointly, as more fully described herein, was willful within the meaning of 73 P.S. §201-8.

258. The Attorney General has determined that these proceedings to enjoin Abbott's and Fournier's conduct are in the public interest.

259. The Commonwealth of Pennsylvania therefore seeks the entry of a permanent injunction restraining Abbott's and Fournier's unlawful conduct and mandating corrective measures pursuant to 73 P.S. §201-4.

260. The Commonwealth of Pennsylvania also requests that the Court require Abbott and Fournier to restore to the Commonwealth of Pennsylvania and Pennsylvania Consumers monies acquired from the sale of its prescription drugs, TriCor, during the period of time Defendant's unlawful conduct took place, pursuant to 73 P.S. §201-4.1.

261. In addition, and in light of Abbott's and Fournier's willful and improper conduct as herein described, the Commonwealth of Pennsylvania requests that the Court award a civil penalty to the Commonwealth of Pennsylvania not exceeding:

a. as to affected Pennsylvania Consumers under the age of sixty (60) years, $1,000.00 per violation; (b) and as to affected Pennsylvania Consumers sixty (60) years of age or older, $3,000.00 per violation.

262. Abbott is liable for its actions and the actions of its co-conspirators for each of these violations as independent unfair and deceptive acts in violation of the UTPCPL, and for its course of conduct comprising an unfair and deceptive practice in violation of the UTPCPL.

263. Fournier is liable for its actions and the actions of its co-conspirators for each of these violations as independent unfair and deceptive acts in violation of the UTPCPL, and for its course of conduct comprising an unfair and deceptive practice in violation of the UTPCPL.

264. As a result of Abbott's and Fournier's unfair and deceptive trade practices, the Commonwealth of Pennsylvania and Pennsylvania Consumers have suffered and will continue to suffer ascertainable loss and damages in an amount to be determined at trial.

265. Accordingly, the Commonwealth of Pennsylvania, on behalf of itself and Pennsylvania Consumers, seeks all relief available, including treble damages, restitution, disgorgement, and/or civil penalties, under the UTPCPL.

266. Defendants' combinations or conspiracies had the following effects: (1) fenofibrate price competition was restrained, suppressed and eliminated throughout Pennsylvania; (2) fenofibrate prices were raised, fixed, maintained and stabilized at artificially-high levels throughout Pennsylvania; (3) Commonwealth of Pennsylvania and Pennsylvania Consumers were deprived of free and open competition; and (4)

Commonwealth of Pennsylvania and Pennsylvania Consumers paid supracompetitive, artificially-inflated prices for fenofibrate.

267. During the relevant period, Defendants' illegal conduct had a substantial effect on Pennsylvania residents.

268. As a direct and proximate result of Defendants' unlawful conduct, the Commonwealth of Pennsylvania and Pennsylvania Consumers have been injured in their business and property and are threatened with further injury.

269. By reason of the foregoing, defendants have entered into agreements in restraint of trade and have monopolized in violation of Pennsylvania common law. Accordingly, the Commonwealth of Pennsylvania, on behalf of itself and Pennsylvania Consumers, seeks all relief available, including damages, restitution and/or disgorgement, under Pennsylvania common law proceeding pursuant to 73 P.S. §732-204 (c).

270. As set forth above, Abbott and Fournier, individually and jointly, have been unjustly enriched as a result of engaging in the following practices with respect to the Commonwealth of Pennsylvania and Pennsylvania Consumers.

a. obtaining multiple patents through inequitable conduct and improperly listing these patents with the Food and Drug Administration; (b) knowing they were obtained improperly and then filing sham patent litigation for the purpose of foreclosing and delaying competition in the market for fenofibrate; (c) forcing the market to convert to a new formulation before generic entry by reformulating TriCor with only minor changes to the form and dosage strength that did not provide any significant new clinical benefit for the purpose of eliminating the generic bioequivalent AB-rating for the prior formulation; (d)

creating an artificial product differentiation as a marketing tool to convince physicians to stop writing prescriptions for the old formulation and to write prescriptions only for the new formulation; (e) stopping promotion and sales of the previous TriCor formulation upon the introduction of the new formulation; (f) removing the old TriCor formulation from the market, so as to make it commercially unavailable by the time a generic competitor could enter the market; and (g) interfering with the normal and customary channels of distribution used by generics.

271. The Commonwealth of Pennsylvania and Pennsylvania Consumers were purchasers, reimbursers, and/or end payors of Abbott's and Fournier's drug, TriCor, and have paid amounts far in excess of the competitive price for TriCor and generic fenofibrate that would have prevailed in a competitive and fair market.

272. Abbott and Fournier, individually and jointly, knew of and has appreciated and retained, or used, the benefits of the Commonwealth of Pennsylvania and Pennsylvania Consumers' purchases of its drug, TriCor, at amounts far in excess of the competitive price. Defendants manipulated the patent process and the FDA Orange Book listing process and filed sham litigation to enforce the improperly obtained and listed patents to eliminate consumer choice of generic fenofibrate. Each of these acts was intended to increase the market share of TriCor thereby increasing its sales and profits.

273. For those customers that purchase directly or indirectly from Abbott at artificially-inflated and supra-competitive prices, Abbott's and Fournier's increases to prices that would have prevailed in a competitive and fair market directly benefit Abbott in the form of increased revenues.

274. Based upon Abbott's and Fournier's conduct set forth in this complaint, it would be inequitable and unjust for Abbott and Fournier, individually and jointly, to retain such benefits without payment of value.

275. Abbott and Fournier, individually and jointly, will be unjustly enriched if it is permitted to retain the direct or indirect benefits received or used resulting from the purchase of TriCor by the Commonwealth of Pennsylvania and Pennsylvania Consumers. The Commonwealth of Pennsylvania, on behalf of itself and Pennsylvania Consumers, seeks to recover the amounts that unjustly enriched Abbott and Fournier, individually and jointly.

276. The Commonwealth of Pennsylvania and Pennsylvania Consumers are therefore entitled to equitable relief in the form of an injunction, restitution and disgorgement, legal relief in the form of damages and any other relief the Court deems appropriate.

South Carolina

277. Plaintiff State of South Carolina realleges and incorporates all of the allegations above from paragraphs 1 through 154.

278. South Carolina represents the South Carolina Medicaid Program ("South Carolina Medicaid"), the South Carolina Employee Insurance Program ("South Carolina EIP"), and South Carolina consumers in this action.

279. Abbott and Fournier's conduct constitutes "unfair methods of competition and unfair or deceptive acts or practices" under §39-5-20 of the South Carolina Code of Laws.

280. South Carolina Medicaid and South Carolina EIP are represented in an individual capacity pursuant to §39-5-140(a). Abbott and Fournier's conduct constitutes a "willful or knowing violation of §39-5-20" under §39-5-140(d), and thus South Carolina seeks to recover treble damages under §39-5-140(a) on behalf of South Carolina Medicaid and South Carolina EIP for all purchases of TriCor made by South Carolina Medicaid and South Carolina EIP during the relevant time period.

281. South Carolina consumers are represented in a statutory parens patriae capacity under §39-5-50 and a common law parens patriae capacity. South Carolina consumers are defined as any natural person, corporate entity, or government entity that purchased TriCor in South Carolina. Pursuant to §39-5-50(b), South Carolina seeks that this Court restore unto South Carolina consumers any ascertainable loss incurred in making any payments for purchases of TriCor. Pursuant to §39-5-50(a), South Carolina seeks injunctive relief to prohibit Abbott from engaging in the conduct described in this complaint.

282. Abbott and Fournier's conduct constitutes a "willful or knowing violation of §39-5-20" under §39-5-110(c). South Carolina seeks an award of civil penalties under §39-5-110(a) in the amount of $5,000.00 per sale of TriCor made in South Carolina.

283. South Carolina seeks attorneys' fees and costs under §39-5-50(a) and §39-5-140(a).

284. South Carolina requests any other relief that this Court deems appropriate.

Texas

285. Plaintiff State of Texas repeats and realleges each and every allegation set forth in paragraphs 1 through 154.

286. This action is brought in the name of the State of Texas by the Attorney General of Texas, acting within the scope of his official duties under the authority granted to him by the Constitution and the laws of the State of Texas, and specifically under the authority granted by the Texas Free Enterprise and Antitrust Act of 1983, Texas Business and Commerce Code section 15.01 *et seq*.

287. Defendants' actions violate, and the State of Texas is entitled to relief, under the Texas Free Enterprise and Antitrust Act of 1983, Texas Business and Commerce Code section 15.01 *et seq*.

288. The State of Texas requests that it be awarded damages from injury to the state Medicaid Program pursuant to Texas Business and Commerce Code section 15.21(a).

289. The State of Texas further requests that it be awarded civil penalties pursuant to Texas Business and Commerce Code section 15.20.

290. The State of Texas further requests that it be awarded injunctive relief to prevent defendants in the future from engaging in conduct similar to the improper conduct alleged in this complaint pursuant to Texas Business and Commerce Code section 15.20.

291. The State of Texas its costs of this action, including reasonable attorneys' fees, costs, and where applicable, expert fees as provided in Business and Commerce Code section 15.20(b) and Texas Government Code section 402.006(c).

Vermont

292. Plaintiff State of Vermont repeats and realleges each and every allegation contained in paragraphs 1 through 154.

293. Defendants' acts violate, and Plaintiff State of Vermont is entitled to relief under, the Vermont Consumer Fraud Act, 9 V.S.A. Sections 2451-2466.

Washington

294. Plaintiff State of Washington realleges and incorporates all of the allegations from paragraphs 1 through 154.

295. Defendants' acts violate Wash. Rev. Code 19.86, including Wash, Rev. Code 19.86.020, Wash. Rev. Code 19.86.030, and/or Wash. Rev. Code 19.86.040.

296. Plaintiff State of Washington on behalf of itself, its state agencies and as parens patriae for all natural persons who purchased defendants' fenofibrate-based drugs is entitled to recover damages and attorneys' fees under RCW 19.86.090, injunctive relief and restitution under RCW 19.86.080 and civil penalties under RCW 19.86.140.

West Virginia

297. Plaintiff State of West Virginia repeats and realleges each and every allegation contained in paragraphs 1 through 154 with the same force and effect as if here set forth in full.

298. The aforementioned practices by Defendants were in violation of the West Virginia Antitrust Act, W. Va. Codes 47-18-1 *et seq.*, and the West Virginia Consumer Credit and Protection Act, W. Va. Code s 46A-1-101 *et seq.*, and the State of West Virginia, its state agencies, and political subdivisions, and the natural persons it represents are entitled to relief there under.

Prayer for Relief

Accordingly, the Plaintiff States request that this Court:

1. Adjudge and decree that Abbott and Fournier violated sections 1 and 2 of the Sherman Act, 15 U.S.C. §§1, 2;

2. Adjudge and decree that the foregoing activities violated each of the state statutes enumerated in this Complaint;

3. Enjoin and restrain, pursuant to federal and state law, Abbott and Fournier, their affiliates, assignees, subsidiaries, successors, and transferees, and their officers, directors, partners, agents and employees, and all other persons acting or claiming to act on their behalf or in concert with them, from continuing to engage in any anticompetitive conduct and from adopting in the future any practice, plan, program, or device having a similar purpose or effect to the anticompetitive actions set forth above;

4. Award to Plaintiff States any other equitable relief as the Court finds appropriate to redress Defendants' violations of federal or state antitrust law or restore competition;

5. Award to each Plaintiff State the maximum civil penalties allowed by law;

6. Award to each Plaintiff State treble damages for overcharges paid by State entities or the State's purchasers of TriCor;

7. Award to each Plaintiff State any other statutory damages, restitution or equitable disgorgement for the benefit of the state and its consumers as appropriate under each state's law;

8. Award to each Plaintiff State its costs, including reasonable attorneys' fees; and as may be appropriate under state law, expert witness fees and investigation costs;

9. Order any other relief that this Court deems proper.

Jury Trial Demanded

The Plaintiff States demand a trial by jury of all issues so triable in this cause.

Dated: April 18, 2008

Respectfully submitted,

THE PLAINTIFF STATES

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